REVIEW ARTICLE

Review of invertebrate biological control agent regulation in Australia, New Zealand, Canada and the USA: recommendations for a harmonized European system

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Abstract

Europe lags far behind Australia, New Zealand, Canada and the USA in terms of implementing regulatory procedures for the import and release of invertebrate biological control agents (IBCAs). A number of standards, documents and guidelines have been produced over recent years in an attempt to harmonize regulation of IBCA introduction into Europe. Despite these efforts, the number of member countries implementing any form of IBCA regulation remains low, with many industries, biological practitioners and regulators fearing that a regulatory system would render the process of approval for IBCA introduction into a country costly and time consuming. Europe's priority is therefore to formulate a regulatory system that will be readily approved of and adopted by all member countries. In this paper we review the current regulatory processes operating in Australia, New Zealand, Canada and the USA. There is potential for Europe to benefit from the years of experience that these countries have in IBCA regulation. We therefore propose recommendations based on features of the regulatory processes in each of the four countries that work well and that could be adopted to generate a workable Europe-wide regulatory system.

Introduction

Countries such as Australia, New Zealand, Canada and the USA are far ahead of Europe in terms of regulating the import and release of exotic invertebrate biological control agents (IBCAs). These countries boast many years of experience with the implementation of classical biological control programmes, having long been recipients of invasive alien pest species (Coulson et al. 2000; Sheppard et al. 2003). The importance of IBCA specificity for the safety of biological control programmes was recognized during the relatively early years of biological control implementation in these countries (Waage 1997). Furthermore, as the practice of exotic IBCA import and release became more widely adopted, assessments to ensure specificity of exotic IBCAs began to be developed and implemented. Australia was one of the first countries to implement some form of legislation and risk assessment for exo-

tic IBCAs when it introduced its Quarantine Act of 1908. However, not all IBCAs have historically been subject to the same degree of regulation. Specificity testing for weed IBCAs was developed first because of the more obvious threat that introduced phytophagous insects posed to economically valuable crops (Waage 2001; Sheppard et al. 2003). It thus followed that legislation and administration for IBCA regulation usually fell under the national plant quarantine service and focused mainly on plant protection and the need to prevent introduced IBCAs from becoming agricultural pests (Waage 1997; Harrison et al. 2005). Concerns about the additional risk of introduced IBCAs to biodiversity in non-agricultural ecosystems arose much more recently (Delfosse 2005; Harrison et al. 2005). The departments responsible for the environment in New Zealand and Australia became involved with the regulatory process in the late 1990s and pre-release studies then required the incorporation of environmental impact assessments.

Specificity testing for exotic IBCAs of invertebrate pests has lagged behind that of weed IBCAs because of the traditional lack of concern for non-target effects on invertebrates (Waage 2001; Sheppard et al. 2003; Van Driesche 2004). Only relatively recently was the biological community faced with criticism regarding the absence of data on the potential threat of exotic entomophagous IBCAs, especially to native beneficial and endangered invertebrate species and to biodiversity. As such, similar legislation for the purpose of regulating entomophagous IBCAs was implemented in Australia, New Zealand, Canada and the USA only within the last 10 years, under the same legislation and procedures as for weed IBCAs. To date, none of these four countries impose regulations for movement and release of native IBCAs, except New Zealand for cases where the IBCA in question is a protected species.

Europe as a continent, in contrast, lags behind these countries in terms of experience in classical biological control implementation, having traditionally been the source rather than the recipient of a large number of alien invasive pest problems (Greathead 1976; Waage 1997; Kuhlmann et al. 2005). Over more recent years however, Europe has witnessed an increase in the establishment and spread of exotic plant and invertebrate pest species, their introduction resulting largely from the escalation in tourism and international trade (Bigler 2001). In response to the associated costs of these invasive species to human activity and biodiversity, interest in the implementation of classical biological control programmes has grown, heightened further by the pressure to avoid chemical control and its associated problems (Waage 1997; Sheppard et al. 2006). Over the last four decades, Europe has also rapidly increased its focus on growing crops in glasshouses and polythene tunnels. These environments have proved ideal for the proliferation of imported pests, which in turn has created numerous opportunities for the application of inundative biological control, a strategy involving multiple releases of native and/or exotic IBCAs. Today, inundative biological control is one of the major pest management strategies used across Europe in these protected crop environments (Bigler et al. 2005a).

Some European countries have already established their own well-organized systems for regulating the introduction and release of exotic IBCAs (Bigler 2001; Bigler et al. 2005a; Loomans 2007); however, there has been a growing interest over recent years to introduce a unified scheme across all European member countries. The first discussions regarding the implementation of such a harmonized regulatory procedure in Europe took place at a joint workshop in 1997 between the European and Mediterranean Plant Protection Organisation (EPPO) and CABI (EPPO 1997). The outcome was that the workshop endorsed the Food and Agriculture Organisation of the United Nations (FAO) Code of Conduct for the Import and Release of Exotic Biological Control Agents, which had been published the previous year as the International Standard for Phytosanitary Measures No. 3 (IPPC (International Plant Protection Convention) 1996). However, the workshop recommended that guidelines be developed to meet European needs with respect to the different legislations and regulations. There have since been a number of initiatives and associated publications, both on a European and global scale, providing national authorities across Europe with guidelines on how to implement a regulatory system for exotic IBCA introductions, as well as providing information on how dossiers should be compiled and assessed. Those that are specific to Europe or include European countries in their scope are displayed in the timeline shown in table 1.

Yet, despite these initiatives, the implementation of regulatory procedures across Europe over recent years has been sparse (Waage 1997; Bigler et al. 2005a). A survey of 19 European countries conducted in 2004, in preparation for a workshop organized by the International Organization for Biological and Integrated Control of Noxious Animals and Plants, West Palaearctic Regional Section

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Table 1. Summary of initiatives and publications, specific to Europe or including Europe in their scope, relating to the implementation and/or harmonization of an IBCA regulation system

Year	Initiative/publication	Outcome
1996	FAO Conduct for the Import and Release of Exotic Biological Control Agents, ISPM No. 3, IPPC (IPPC (International Plant Protection Convention) 1996)	A standard for countries lacking adequate legislation and procedures to regulate import and to analyze risks related to biological control agents. The document lists the responsibilities of the authorities and importers and exporters of biological control agents
1997	EPPO/CABI Workshop on Safety and Efficacy of Biological Control in Europe (EPPO 1997)	Endorsed the FAO Code of Conduct with recommendations that guidelines be drawn to meet European needs with respect to the different legislations and regulations. Recommended a certification system be implemented instead of a registration procedure, to reduce stringency of the regulatory system. An expert panel was established to draw up more specific guidance documents and prepare a 'positive list' of invertebrate biological control agents (see next three events)
1999	EPPO Guidelines for the First Import of Exotic Biological Control Agents for Research Under Contained Conditions (EPPO 1999)	Guidance stressing the importance of a two-step system for importation and release, i.e. EU countries should first establish a regulatory process for the import of exotic organisms for research under containment, the data from which can be used later for decision to approve importation of organism for release. Information to be included in an applicant's dossier is provided
2001	EPPO Guidelines for Import and Release of Exotic Biological Control Agents (EPPO 2001)	As above but also provides information on how the authority should examine a dossier
2002	List of Biological Control Agents Widely Used in the EPPO Region (EPPO 2002)	A 'positive list' of invertebrate biological control agents that are widely used in the EPPO region without any reports on adverse effects. The aim of this list was to facilitate and speed up the use of invertebrate biological control agents in the EPPO region and to regularly adapt the list depending on new information
1998–2002	EU-funded ERBIC (Evaluating Environmental Risks of Biological Control Introductions into Europe) research project	A proposal for the environmental risk assessment of exotic natural enemies in inundative biological control (van Lenteren et al. 2003). This paper was the first to present detailed criteria for risk assessment as well as a system for ranking biological control agents in terms of their environmental safety
2003	OECD Guidance for Information Requirements for Regulations of Invertebrates as Biological Control Agents (OECD 2004)	Document proposing guidance to member countries on information requirements for the characterization and identification of the organism, the assessment of safety and effects on human health, the assessment of environmental risks and the assessment of efficacy of the organism. The decision of whether and how these organisms are regulated is left to the member countries
2003	IOBC/WPRS Commission for the Harmonization of Regulation of Invertebrate Biological Control Agents	Document on information requirements for import and release of invertebrate biological control agents in European countries (Bigler et al. 2005b). This document provides more specific advice to applicants and national authorities on information required for risk assessment compared with the EPPO and OECD documents. It reduces data requirements for facilitating regulation but still respects concerns related to human and environmental safety
2005	FAO Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and Other Beneficial Organisms, ISPM No. 3, IPPC (IPPC 2005)	A revised version of the original FAO Code of Conduct (IPPC (International Plant Protection Convention) 1996), which extends its range from classical biological control to inundative biological control, native natural enemies, micro-organisms and other beneficial organisms and also includes evaluation of environmental impact
2006	Environmental Impact of Invertebrates for Biological Control of Arthropods: Methods and Risk Assessment (Bigler et al. 2006)	This book was compiled by 25 scientific experts at a workshop in Switzerland in 2004 to address the issue that required information and data for the submission of a dossier to the national authority were often not available to the European community. The book therefore presents a framework of environmental risk assessment for the preparation of the dossiers by the applicants and for their evaluation by national authorities
2006–2008	EU Policy Support Action REBECA 'Regulation of Biological Control Agents' (REBECA 2007)	The aim of this ongoing project is to develop a balanced system for regulation of biological control agents (micro- and macro-organisms), semiochemicals and botanicals. It is expected therefore in a few years that EU members and other EU countries may regulate invertebrate biological control agents under uniform principles

(IOBC/WPRS) Commission on Harmonization of Regulation of Invertebrate Biological Control Organisms revealed that despite all countries investigated having national legislations in place, an active regulatory process has only been implemented to some degree in eight countries (Austria, Czech Republic, Denmark, Hungary, Norway, Sweden, Switzerland and UK). Five countries are still working on the design and implementation of a regulation system (Finland, Germany, Netherlands, Slovenia and Spain) and six countries have no regulation implemented yet and would not have a regulatory system in place in the foreseeable future (Belgium, France, Greece, Italy, Poland and Portugal) (Bigler et al. 2005a).

Almost all European countries are signatories of the Convention on Biological Diversity (CBD) and are therefore obliged to prevent the introduction of alien species and, when prevention fails, to control as far as possible those exotic species that threaten indigenous ecosystems, habitats or species (CBD 2007). Regulatory procedures for the import and release of exotic IBCAs are therefore an absolute requirement across Europe, a fact that is accepted by the biological control industry (Blum et al. 2003).

However, one of the main concerns in Europe is that a regulatory system would render the process of approval for IBCA introduction and release into a country both costly and time consuming. Extensive delays associated with environmental risk assessments could potentially multiply biological control programme costs, leaving industries struggling to afford to run them and research organizations unable to attain funding to undertake such projects. It is necessary therefore that a Europe-wide regulatory system is devised that ensures safe and effective practice of biological control, while remaining realistic and manageable for those involved. Not only will such a system facilitate the process of introduction and release of exotic IBCAs into European countries, but it will also increase public confidence in biological control, the importance of which is widely recognized. Europe must therefore endeavour to formulate such a regulatory system that will be readily approved of and adopted by all member countries.

Rather than devising a regulatory procedure from scratch, Europe has the advantage of being able to benefit from the years of experience that Australia, New Zealand, Canada and the USA have had in operating regulatory systems. Our first aim in writing this paper was to provide a review of the regulatory procedures in place for the introduction and release of IBCAs of invasive plants and invertebrates in these four countries. By studying and comparing the different systems they operate, our second objective was to determine components that work well that could be recommended for adoption and incorporation into a workable regulatory framework to suit the needs of Europe. The research for this paper was carried out as part of a study within the 'Macrobials' work package of the European Union (EU)-funded policy-oriented research-specific support action, 'Regulation of Biological Control Agents' (REBECA) (REBECA 2007). The REBECA project is reviewing the regulation of biological control agents (microbials, botanicals, semiochemicals and macrobials) for plant protection in the EU. This paper provides a timely forum and review article on IBCA regulation, intended to stimulate debate within the REBECA network and elsewhere in Europe in this important and fast-progressing area of research and policy.

Materials and Methods

Several sources were used to collect the information contained in this paper. The main sources were the websites of the governmental administrative bodies of each country from which much of the required information was either readily available or easily obtainable from documents accessed via the links provided. In addition, further information was gleaned from published papers and documents as well as from consultations with government employees and scientists directly involved with the regulatory processes.

Before this paper was compiled, a set of criteria was devised in order to bring some focus to the information retrieved and allow for easy comparison between countries of the data requirements and procedures in place. This paper is therefore structured in a way that presents the same information for each country in turn under the following set of sub-headings, representing the chosen criteria:

- Legislation and administration;
- Application procedure;
- Decision-making process;
- Decision maker;
- Data requirements;
- Time frame;
- Availability of information about regulation process to aid applicants;
- Public participation;
- Length of validity of permit;

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- Is there a 'safe list' of IBCAs that are exempt from regulation?

For greater ease of comparison, a table has been compiled displaying a summary of selected information about the regulatory procedures in each of the four countries (table 2).

Results

Australia

Legislation and administration

The legislations governing the import and/or release of biological control agents are the Quarantine Act (1908), administrated by the Department of Agriculture, Fisheries and Forestry (DAFF) and the Environment Protection and Biodiversity Conservation Act (1999; EPBC Act), managed by the Department of the Environment and Water Resources (DEW). In addition, the Biological Control Act (1984) can be used when there is controversy about the release of the biological control agent and this is handled by a council comprising ministers across relevant departments from federal and state governments.

Quarantine Act and DAFF[1]. DAFF is responsible for approval of the importation of exotic biological control agents for the control of weeds and invertebrates under the Quarantine Act 1908. DAFF is also responsible for approval of host specificity test lists and release of the biological control agents (DAFF 2007). Biosecurity Australia within DAFF (DAFF-BA) assesses the importation of the agent and consults with co-operators on the host specificity test list and release applications. Co-operators include the Australian Quarantine and Inspection Service within DAFF (DAFF-AQIS), DEW (see below), the Commonwealth Scientific and Industrial Research Organization (CSIRO), and relevant state/territory government departments or research organizations.

EPBC Act and DEW. DEW regulates the import and/or release of exotic biological control agents under the EPBC Act. An application to release a classical biological control agent through DEW is an application to have the agent species added to the Live Import List (DEW 2007a) under the EPBC Act. Although the list does not actually specify the species as 'biological control agents', the list is inclusive of all permitted live animals[2].

DAFF and DEW have different perspectives regarding the risks of biological control agents. DAFF has broad responsibilities for managing potential risks to primary industries, agriculture and environment, whereas DEW focuses on managing potential risks to the environment. Furthermore, administration of biological control agent applications operates differently within the two departments. DAFF-BA consults directly with co-operators by distributing the submitted applications to them. DEW publishes the Terms of Reference for the application on their website for public comments and notifies its listed stakeholders including the heads of other relevant federal and state departments. The process is streamlined, however, such that the same application form for import can be sent separately to both departments and the information requirements for release application are specified in the same protocol (DAFF 2007).

Biological Control Act and its use. Australia has specific legislation for biological control agents, named the Biological Control Act 1984. This Act was drafted in response to controversy surrounding the proposed biological control of Paterson's curse, *Echium plantagineum* L. The Biological Control Act 1984 is the Commonwealth legislation that applies only to the Australian Capital Territory and the external Australian territories. To ensure this legislation applies uniformly throughout Australia, all states have passed their Biological Control Acts to mirror the Commonwealth legislation because it is the states, not the Commonwealth, that have the jurisdiction to legislate on the biological control issue. The Commonwealth and State Acts are only used for projects of high benefit potential where there is controversy about the release of a biological control agent. To date, no biological control agents have been approved for release through the Acts before their detection in the Australian environment, with the exception of some organisms to control Paterson's curse. These Acts protect the agency undergoing the biological control activities if the benefit cost ratio comes out in its favour and the protection only applies in the jurisdiction in which an application for approval is made. When the Acts are invoked, a public consultation government-funded benefit

[1]Please note that DAFF is in the process of reviewing its protocol to deal with the import and release of biological control agents. The process described in the present paper may be modified resulting from the review. Readers are referred to DAFF website (DAFF 2007) under Biosecurity Australia for updates on the protocol.

[2]DEW's lists only include animals. DEW refers the applicants who want to import new species of live plants to contact DAFF for advice.

Table 2. Summary of regulatory procedures in Australia, New Zealand, Canada and the USA

	Australia	New Zealand	Canada	USA
Legislation	Biological Control Act (1984) Quarantine Act (1908) Environment Protection and Biodiversity Conservation Act (1999)	Hazardous Substances and New Organisms Act (1996)	Canadian Plant Protection Act (1990)	Plant Protection Act (2000) Endangered Species Act (1973) National Environmental Policy Act (1969)
Administration	DAFF and DEW	ERMA New Zealand	CFIA-PHD (AAFC)	APHIS-PPQ (USDA)
Review of release applications	DAFF (representatives from federal and state government departments and research organizations) and DEW (representatives from federal and state government departments)	ERMA New Zealand Authority	BCRC (federal, provincial and university specialists, scientists, consultants), TAG* and representatives from Mexico and USA	TAG* and representatives from Canada and Mexico
Application procedure	DAFF: (i) Approval to import into containment for scientific research (ii) Approval of host specificity test list (iii) Approval for release into environment DEW: (i) Approval to import into containment for scientific research (ii) Amendment to Live Import List	ERMA New Zealand: (i) Approval to import into containment for scientific research (ii) Approval for environmental release MAF Biosecurity: Approval to import	CFIA Import Office: (i) Approval to import into containment for scientific research (ii) Approval for environmental release	APHIS-PPQ and TAG*: (i) Approval to import into containment for scientific research (ii) Approval for environmental release TAG* and FWS: Approval of host specificity test list
Data requirements for full release	Target pest information, biological control agent information and its potential to control target, simple cost-benefit analysis, details of proposed action and host specificity testing data	Full ecological, human health, economic, social and cultural risk, cost and benefit analysis	Data conforming to NAPPO guidelines: details of proposed action, target pest information, biological control agent information, environmental and economic impact of proposed release (including host specificity testing data) and plans for post release monitoring	Environmental and biological assessments, plus data conforming to NAPPO guidelines: details of proposed action, target pest information, biological control agent information, environmental and economic impact of proposed release (including host specificity testing data) and plans for post release monitoring
Decision basis	DAFF: science-based review DEW: comments from federal and state government departments and public	Full ecological, human health, economic, social and cultural risk, cost and benefit analysis and public comments	Science-based peer review	Science-based peer review
List of approved biological control agents	DEW Live Import List	All approved organisms are listed on a database	List of previously released 'safe' biological control agents	'Safe list' of 'APHIS-permitted beneficials imported into the USA from other countries'
Length of validity of approval/permit to release	Indefinite but may be reviewed in 5 years by DEW	Indefinite	3 years	Up to 3 years
Regulation of indigenous species	None	None unless protected native species	None	None
Stages of public participation	DEW process: (i) Approval to import into containment for scientific research (ii) Approval for environmental release	(i) Approval to import into containment for scientific research (ii) Approval for environmental release	None	APHIS-PPQ process: approval for environmental release

Table 2. (Continued)

	Australia	New Zealand	Canada	USA
Time frame for processing import and release applications	DAFF-BA: approx. 90 working days (depending on issues between applicant and co-operators) DEW: between 5 and 12 months	100 working days (unless waiver agreed) for publicly notified applications	Approximately 6 months	Approximately 18 months
Fees	DAFF: AU$ 180 (approx. 108 EUR): import permit and renewals DEW: no fee	NZ$ 33 750 (approx. 17 000 EUR): full environmental release NZ$ 11 250 (approx. 5700 EUR): permit to import into containment	CA $15 (approx. 10 EUR): permit to import for scientific research purposes CA $35 (approx. 24 EUR): permit to import for purposes other than research	No fee

DAFF-BA, Department of Agriculture, Fisheries and Forestry – Biosecurity Australia; DEW, Department of the Environment and Water Resources; ERMA New Zealand, Environmental Risk Management Authority; MAF, Ministry of Agriculture and Forestry; CFIA-PHD, Plant Health Division of the Canadian Food Inspection Agency; AAFC, Agriculture and Agri-Food Canada; BCRC, Biological Control Review Committee; APHIS-PPQ, Animal and Plant Health Inspection Service of Plant Protection and Quarantine; USDA, United States Department of Agriculture; TAG, Technical Advisory Group; FWS, Fish and Wildlife Service.
*TAG only involved in weed biological control projects.

cost analysis has to be initiated but this usually occurs if there are assumed high benefits to Australia (in real terms and over costs). Thus, where there is no controversy, the biological control programmes are established and implemented outside these Acts.

Application procedure

The application process for the import and release of entomophagous and phytophagous biological control agents is shown in a flow chart in fig. 1. Specifically, the release of biological control agents of weeds and invertebrates involves the following three steps:

- The potential biological control agent is identified and approval is sought to import it into quarantine containment. This stage is essentially the nomination and justification of the potential target species before approval to import a biological control agent is granted:
- An application is submitted for acceptance of a list of species and testing protocols against which the potential agent will be tested for specificity;
- An application is submitted that both seeks approval for release of the biological control agent and to have this species added to the live import list. The application includes a risk assessment, the most detailed parts of which are the results and interpretation of the host specificity tests of the agent carried out on the accepted list of test species.

Post-release monitoring of establishment, efficacy and non-target effects is required but not enforced by either DAFF or DEW.

Approval for import into quarantine containment. Completed application forms are submitted to DAFF and DEW separately. Included with the application form are the application fees, the address of the AQIS-approved quarantine facility with its appropriate containment level, specification of the host material or the media used for the transportation of the agent and basic cost-benefit assessment information about the proposed biological control agent and its target (see 'Data requirements' below). This information is sufficient to satisfy the legislative requirements for DAFF, as well as for DEW to amend the Live Import List to include the proposed biological control agent. Specifically, DEW requirements are a draft Terms of Reference for an assessment of the potential impacts of the proposed amendment on the Australian environment. Voucher specimens must be deposited in a recognized collection.

Approval of host specificity test list. In the current DAFF protocol, approval of the host specificity test list is a

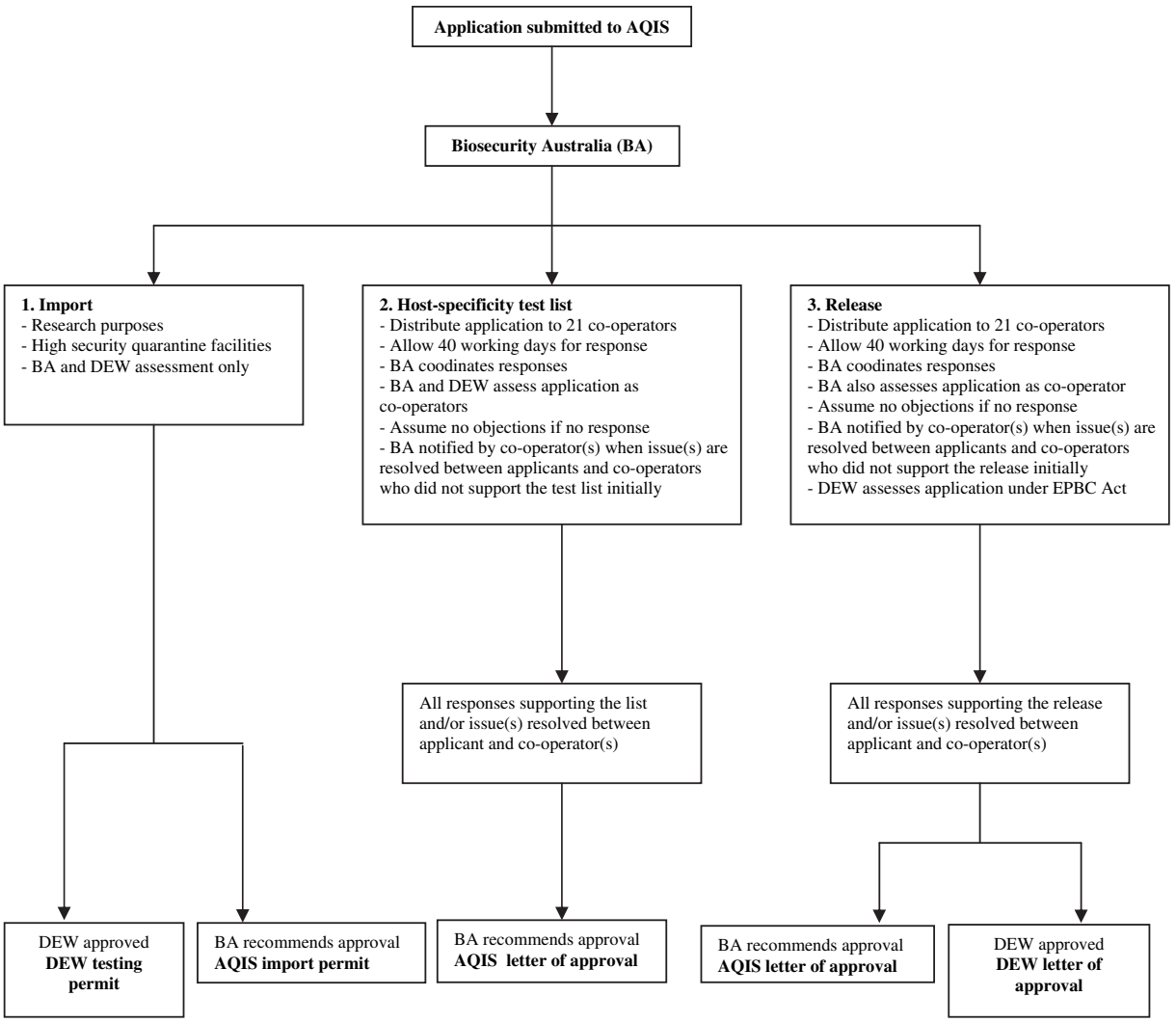

Fig. 1. Australian review process for biological control agent applications [from the Department of Agriculture, Fisheries and Forestry website (DAFF 2007)]. Note that original DEH is updated here as DEW. AQIS, Australian Quarantine Inspection Service; DEW, Department of the Environment and Water Resources; EPBC, Environment Protection and Biodiversity Conservation Act

separate step. DEW does not directly approve the host specificity test list but it is one of the co-operators that DAFF-BA consults with and has the capacity to suggest changes to the list and, like any other co-operator, the ability to veto approval of the test list if their suggested changes are not accepted by the applicant.

Release approval. Separate approvals are required from DAFF and DEW and the applicant must therefore submit their application to release to both departments. The same application can be used for both departments.

A qualified DAFF-AQIS regional officer, such as a quarantine entomologist, will supervise the physical release of the agent from the quarantine facility.

Decision-making process

An overview of the Australian decision-making process for IBCA import and release is displayed in fig. 1.

Approval for import into quarantine containment. Approval must be sought from both DAFF and DEW before an agent of any sort can be imported into an Australian quarantine approved facility.

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DAFF approval: A completed import application form is sent to DAFF-AQIS, which passes it on to DAFF-BA for advice. DAFF-BA assesses the application, if necessary, consulting with relevant expertise, and provides recommendation on whether or not the import should be approved and what conditions should be followed if the approval is given. Each application is assessed on a case-by-case basis. It should be noted that DAFF-BA only provides recommendations and DAFF-AQIS makes the final decision. After receiving the recommendations from DAFF-BA, DAFF-AQIS would issue an import permit. The permit will include a condition specifying that the DAFF-AQIS permit is not valid unless accompanied by a DEW permit (see below).

DEW approval: A completed application form and draft Terms of Reference are submitted to DEW. DEW publishes the draft Terms of Reference on its Public Notices web page for 10 business days to enable the public to comment on the proposed import. Public comments, if any, are collated and sent to the applicant along with suggested changes to the draft Terms of Reference. The applicant makes the required changes and forwards the revised draft Terms of Reference back to DEW. DEW issues a testing (import) permit when the Minister or his Delegate approves the Terms of Reference. Containment requirements are the same as the ones specified by AQIS and this is ensured by stating that the DEW testing permit is not valid unless accompanied by an AQIS permit. The testing permit allows studies to be conducted in a quarantine facility, if necessary, to meet the Terms of Reference and to produce a draft of the required environmental assessment (EA). A single testing permit will allow multiple consignments of the species to be imported for testing over a period of 6 months. Voucher specimens of all tested agent material must be deposited in a recognized institution.

Approval of host specificity test list[3]*. DAFF approval:* After receiving the application, DAFF-BA distributes the applicant's list and application report to 21 co-operators who are given a period of 40 business days to respond. DAFF-BA itself, as well as DEW and DAFF-AQIS, also act as co-operators. DAFF-BA is responsible for coordinating the co-operators' responses. BA does not progress the application unless responses from all the co-operators are received including those having no objections. All the comments from co-operators are forwarded to the applicant to respond. If the co-operators do not support the initial list or want to add species to the list, the applicant is required to resolve any issue(s) directly with these co-operator(s).

Release approval. DAFF approval: The approval procedure for release application is the same as for the host specificity test list application explained above. Moreover, the conditions of release include the requirements that voucher specimens of all life stages of the agent must be deposited in a recognized collection as well as AQIS own collections in different states.

A qualified AQIS regional officer, such as a quarantine entomologist, will supervise the physical release of the agent from the quarantine facility. If new biological control agent material is to be imported a new permit to import application must be submitted.

DEW approval: The applicant submits to DEW a draft risk assessment report addressing the approved Terms of Reference. DEW publishes the draft risk assessment report on the Public Notices web page for a minimum of 20 business days and advises stakeholders. At this time, the Minister seeks comment from appropriate state, territory and Australian Government Ministers on the proposed import. Comments received on the draft risk assessment report are forwarded to the applicant for incorporation into the final report. The applicant must address any comments received on the draft risk assessment report. The revised final risk assessment report is sent to the Minister for DEW who makes a decision on whether to amend the live import list. If the Minister approves the application, the list will be formally amended to include the agent species through publication in the Australian Government Gazette. It is then tabled in federal parliament for 15 days of parliamentary session. Review of amendments to the Live Import List can be made within 5 years of the amendment being made. Public negatively affected by the decision may request a written explanation (Sheppard et al. 2003).

Once inside Australia, the agent can be released throughout all the states and territories unless its status changes and it (a) loses its release permit following review or (b) becomes a declared noxious species in one of the states or territories in which case it cannot be moved into that state or territory.

Decision maker

Within DAFF, the Director of Animal and Plant Quarantine (the Secretary of DAFF) (or the delegate in AQIS) is the decision maker on whether or not to

[3]This may not be treated as a separate step after the current review of DAFF's protocol.

approve import and/or release of the new biological control agent. Within DEW, the Minister for the Environment and Water Resources is responsible for endorsing the amendment of the Live Import List to include the new biological control agent.

Data requirements

Information requirements and processing of biological control agent applications were devised by DAFF in consultation with DEW. Both departments require similar information for import and release applications.

Information required to import agent into containment. The information required for applications to import IBCAs should be sufficiently comprehensive to allow an appropriate assessment to be made. The application package should include information on the target pest species as well as the biological control agent: e.g. the biology, native and overseas distribution, pest status and economic impact of the target pest species, and biology, native range, source, host range and mode of action against the target of the agent.

The potential for control of the pest target should be addressed and any non-target organisms at risk from the agent and possible interactions that may occur with existing biological control agents should be stated. A simple risk-benefit analysis must be provided in terms of the economic and environmental losses caused by the target and the benefits of its control. If work involving the same species has already been undertaken, then this must be stated and any available information on commonwealth, state and territory legislative controls on the species must be provided. Possible interactions, including conflict of interest with existing biological control programmes should also be considered. For example, if the target species is in the same genus as an introduced agent in an existing biological control programme, the potential agent must be tested against the existing biological control agent. A summary of the proposed activity also needs to be provided as well as details of host specificity. Copies of references cited are required to be attached with the application.

Terms of Reference for the assessment of host specificity are specifically required by DEW.

Information requirements for acceptance of host specificity test list. When applying to DAFF for approval of the host specificity test list, it is necessary first to provide the same detailed information as in the import application. The results of host specificity testing carried out elsewhere, a host specificity test list with justification based on Wapshere's (1974) centifugal-phylogenetic method as well as the methodology of testing that will be used must also be provided. Other information about the number of related species belonging to the same order as the target in Australia (native and introduced) must be given. This information is increasingly presented and accepted using a modernized phylogenetic analytical approach (Briese 2005, 2006), based on published material on molecular phylogenies relevant to the target.

Information requirements for approval to release agent. The application for release of an IBCA must contain all the information presented in the host specificity and import applications, updated where appropriate. The main additional requirement for approval to release a biological control agent is a non-target risk assessment built around the information on the results of host specificity testing. The non-target risk assessment is a quantified response of laboratory evaluation of oviposition, immature and adult feeding and development to maturity on each test species in the format of a scientific publication. This therefore includes a scientifically coherent summary of testing methods used benchmarked against current scientific standards (Sheppard et al. 2005) and, where necessary, appropriate statistics applied. Overseas host records, including literature and discussions with experts can also be provided if not already done so along with any evidence of unexpected agent behaviour or development during the testing. Information regarding the potential biological control agent tested should also be presented including information about the biogeographical origins of the tested population that is proposed for release. The applicant will need to notify an AQIS regional officer about the release and the officer may require information on where, when and how the initial release is to be made. It is recognized that in some cases more information will be required. For some targets and agents, not all points will need to be covered. Some additional information may also be required to ensure that all of DEW Terms of Reference are adequately addressed.

A copy of the approved host specificity test list must be supplied and explanations provided for any variations from the original copy. If such variations to the approved host specificity test list exist, cooperators are not obliged to accept the variations and may ask for further testing. Similarly, the appli-

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cant may add further species to the test list during the testing process.

DEW requires a risk assessment report based on the agreed Term of References.

Fees

A fee of AU $180 (approximately 108 Euros) is charged by AQIS for issuing the permit to import biological control agents into containment. No fees are required for the applications for host specificity test lists or for release of a biological control agent. However, when a permit has expired after the 2 years and renewal is sought, AQIS will charge the same for issuing a new import permit.

Time frame

Approval for import into containment. DAFF will approve an import application within 30 business days if all required information is provided in the application. DEW requires ten business days as a minimum (this is the length of time that the Terms of Reference are posted on their Public Notice website for consultation).

Acceptance of host specificity test. Approval of the host specificity test plant list will require a minimum of 40 business days by DAFF (co-operators are given this time limit to make comments). DEW approval is not required.

Release approval. For release permit applications, a DAFF response can again be expected after a minimum of 40 working days when the co-operators have made comments. DEW however set no time limits. In practice, for an agent where no significant risk issues are evident, the DEW process takes between 5 and 12 months from submission of the release application.

Availability of information about regulation process to aid applicants

The DAFF website has a set of web pages providing a thorough explanation of the biological control agent import process (DAFF 2007). DEW also provides information on their website for applicants, including questions and answers (DEW 2007b).

Public participation

There are two phases of public comment through DEW. The first is prior to importation when the Terms of Reference for the assessment of likely impacts of the agent on the environment are given. The second is with respect to the draft release application. In both cases, the applications are posted on the DEW Public Notice website. The current DAFF protocol does not include public consultation. However, it is likely that a public consultation process will be introduced soon.

Length of validity of the permits

Permit to import into quarantine containment. AQIS' import permit is valid for 2 years and DEW's testing permit expires after 6 months. These permits allow for multiple imports.

Release approval. Approval for release may be reviewed by DEW after 5 years but no review is specified by DAFF.

Is there a 'safe list' of IBCAs that are exempt from regulation?

The species on DEW's Live Import List Part 1 includes the biological control agents permitted by DEW to be imported without prior approval. However, this is not a comprehensive list for biological control agents that have already been approved for release previously. DAFF does not maintain a published list of the released agents. However, any previously released agents may be imported and released again without further approval. The only requirement for such agent is that the new material must be bred for one generation in an appropriate level of quarantine containment facility to eliminate any diseases or parasites associated with the new material. Different strains or biotypes may require further assessment.

Table 2 displays a summary of the Australian regulatory system and its comparison with procedures in New Zealand, Canada and the USA.

New Zealand

Legislation and administration

The Hazardous Substances and New Organisms (HSNO) Act was introduced by New Zealand in 1996 and came into effect for HSNO in July 1998. The purpose of this Act is 'to protect the environment, and health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms'. The introduction of all organisms that are not present in the New Zealand environment, including biological control agents of pests and weeds, falls under this Act and there is an organized process of application and assessment that

must be undertaken to gain approvals. The Environmental Risk Management Authority (ERMA New Zealand) was established under the HSNO Act to implement all processes covered by the Act. ERMA New Zealand is thus responsible for assessing and making decisions on import and release applications for all new organisms, including IBCAs. It is an autonomous Crown Entity, reporting to the Minister for the Environment and overseen by the Ministry for the Environment.

Environmental Risk Management Authority (ERMA New Zealand). ERMA New Zealand consists of the decision-making Authority, the Agency (comprising a chief executive, managers and staff) and Ngā Kaihautū tikanga taiao (Ngā Kaihautū) – a Māori advisory committee.

The Authority is the main governing board of ERMA New Zealand and holds the decision-making power on applications to import, develop, field test or release new organisms. The Authority acts as a quasi-judicial body, having the same immunities and privileges of a district court and the power to operate under 'court-like' procedures, for example, permitting cross-examinations or questions of clarification at public hearings. It comprises six to eight people who are appointed by the Minister for the Environment and who represent a 'balanced mix of knowledge and experience in matters likely to come before the Authority'. They may or may not have a scientific background.

The Agency was set up to carry out operations in support of, or on behalf of, the Authority. The Agency works directly with applicants to facilitate the application process. It also provides support for decision-making, overviews enforcement [which is carried out by the Ministry of Agriculture and Forestry (MAF)], monitors the effectiveness of the Act and promotes public awareness of the risks and benefits of HSNO.

Ngā Kaihautū comprises six to eight members, appointed on the basis of their background and expertise. The Authority appoints these members but they have the freedom to co-opt more people with specific expertise if required. The main responsibility of Ngā Kaihautū is to provide the Authority with independent advice on issues of relevance to Māori (indigenous people), such as, their approach to risk and their principles and concerns.

ERMA New Zealand is financed in part by applicant fees but mostly from government funds. ERMA New Zealand is overseen by the Minister for the Environment and must, according to Crown Entities legislation, adhere to government policy. However, its statutory nature means it remains independent from government influence. The Minister for the Environment can appoint additional members to the Authority for applications that he/she considers to have significant cultural, economic, environmental, ethical, health, international or spiritual effects, or significant effects in an area where ERMA New Zealand lacks sufficient knowledge or experience. The Minister then makes the decision on advice from the Authority. No such intervention event has yet occurred in the last 8 years of the implementation of the Act.

Application procedure

In New Zealand, applicants must apply to ERMA New Zealand for the following approvals in order to import and/or release a candidate entomophagous or phytophagous IBCA:

- Approval to import the IBCA into containment (not always required if safety testing is carried out offshore).
- Approval to import for full or conditional release or approval for full or conditional release from containment of the IBCA.

There is no requirement for post-approval activities under the New Zealand application process. Once an organism has been approved for full release and the release has occurred, it is no longer considered 'new' and so is not subject to HSNO Act regulation. If an IBCA has received a conditional release approval, the MAF (the enforcement agency for ERMA New Zealand) audit the conditions and the organism remains a new organism.

Approval to import into containment. Applications to import a new organism into containment for research purposes must be submitted to ERMA New Zealand. The Authority has discretion to notify the public of receipt of applications to import new organisms into containment, although normally this will not occur unless there is likely to be significant public interest. If the application is publicly notified, then it is subject to a public consultation process. Unless stated otherwise, an approval to import a new organism into containment may be used by any person (not just the applicant). Any approval will have a set of formal containment requirements that must be adhered to by all users and may include approval for a 'field-test'.[4] All new organism imports are also subject to MAF biosecurity quarantine requirements regulated

[4]A field-test under the HSNO Act is considered a containment approval and controls are imposed to ensure that no biological material leaves the field-test site.

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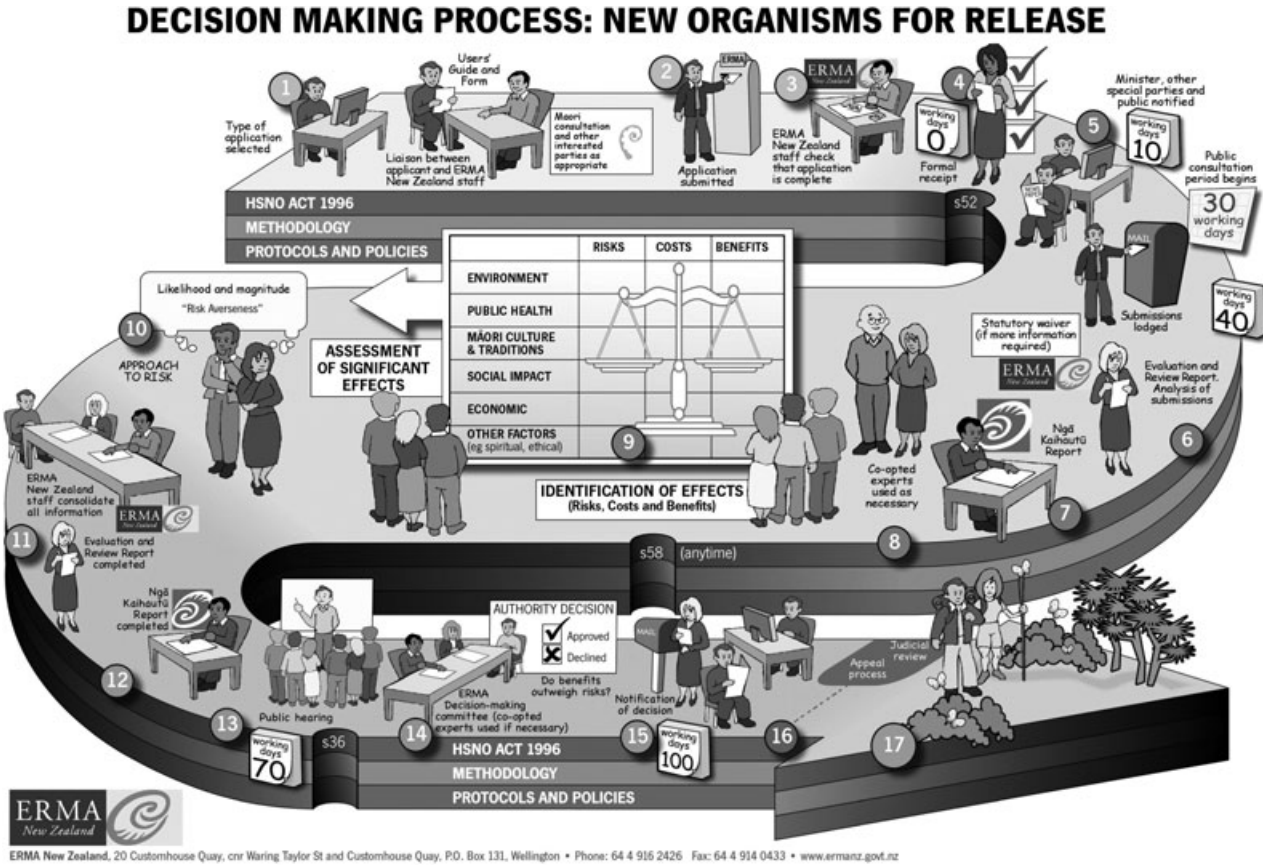

Fig. 2. A diagrammatic representation of the application and approval processes for the full release of a new biological control agent in New Zealand (from Harrison et al. 2005)

under the Biosecurity Act 1993. MAF is responsible for New Zealand's Import Health Standards (IHS), which are designed to prevent accidental or illegal introductions of viable organisms (in this case, associated organisms, such as pathogens).

Approval for full or conditional release. The application procedure for the release of an IBCA in New Zealand comprises a defined series of steps. The proceedings are outlined below and summarized diagrammatically in fig. 2.

Liaison between applicant and ERMA New Zealand staff: The first step in the application process involves a liaison between the applicant and ERMA New Zealand Agency staff. Consultation with Māori, the Department of Conservation and other interested parties will also be recommended when appropriate. This first contact between ERMA New Zealand and the applicant is considered an essential part of the application process, ensuring that key scientific, technical and risk management issues that should be incorporated into the final application are discussed. The potential risks, cost and benefits of the introduction can also be highlighted at this time such that the necessary analyses can be carried out effectively.

Notification of the Minister and public: Following submission of the application, ERMA New Zealand Agency staff check that the application contains adequate information and then issue a formal receipt. The Minister, other interested parties and, if required, the public are then notified about the application and a period of 30 working days is allowed for public consultation. Members of the public can lodge submissions of comments and/or concerns during this period.

Evaluation and review report: ERMA New Zealand Agency staff then initiates an evaluation and review report, incorporating information provided or issues raised in submissions. If more information is required, the process is stalled until the applicant fulfils the requirements. After sufficient further information is provided, the timeline resumes. Ngā Kaihautū also completes a report and co-opted experts are called upon as necessary. ERMA

New Zealand Agency staff consolidates all the information and complete the evaluation and review report.

Public hearing and final decision: If any submitter(s) asks to be heard, a public hearing must be held. This comprises an Authority committee (usually three members), relevant Agency staff, co-opted experts, the applicants and their witnesses and any stakeholders and members of the public who have asked to be heard or wish to attend. The Authority then considers all the information they have received, formulates their decision and notifies the applicant with its decision and reasons for it. All reports are made publicly available. Following any unsuccessful decision, the applicant or other parties can only appeal to the High Court on 'points of law' or seek a judicial review. If approval for release is granted, the applicant must then obtain an Import Permit and an IHS under the Biosecurity Act of 1993 from MAF. With ERMA New Zealand approval for release, together with an Import Permit and an IHS issued by MAF, the new organism can then be imported and released.

Decision-making process

Figure 2 shows a diagrammatic overview of the decision-making process for IBCA import and release in New Zealand.

Approval to import into containment. The Authority assesses each application before deciding whether or not to approve it. Approval of containment applications is largely based on how the applicant proposes to contain the organism. Under the HSNO Act, containment facilities are defined as those that are 'registered by MAF under the Biosecurity Act (1993)'. In making its decision, the Authority will thus look closely at the containment regime proposed by the applicant, which is based largely on requirements set out in the joint Australian Standards/New Zealand Standards 2243.3:2002: Microbiological Aspects and Containment Facilities (Safety in Laboratories) and the appropriate MAF/ERMA New Zealand Joint Standards.

Approval for full or conditional release. The New Zealand approach to assessing IBCA introductions for full release closely matches a full ecological risk, cost and benefit analysis. Decisions by the Authority have to follow detailed criteria set down in the Act as well as in a formal methodology developed in accordance with the HSNO Act. The risk, cost and benefit analysis is based on information provided by the applicant, submissions (from public, government departments, industry and community groups), the Agency, external experts and the Māori Advisory Committee (if relevant). Applications are assessed in accordance with the purpose of the HSNO Act by taking into account various principles and matters it identifies, such as sustainability of native and valued introduced flora and fauna, the intrinsic value of ecosystems, public health, the culture and traditions of Māori, market economy and international obligations. The HSNO Act requires ERMA New Zealand to take into account the need for caution where there is scientific or technical uncertainty and to safeguard against potential adverse effects of HSNO. If the release of a biological control agent poses only a slight risk but its benefits are also modest, ERMA New Zealand's policy would be to avoid taking the risk at all (Sheppard et al. 2003).

In some cases, approval will be given for a conditional release, allowing the organism(s) to be released into the environment but with controls or conditions imposed. This can be applied to a wide range of circumstances including a scientific trial, similar to a field trial, through to full commercial release. The Authority will normally decide upon the nature of the controls imposed on a case-by-case basis. An organism under such a situation remains a new organism under the HSNO Act. Following an amendment to the HSNO Act in 2003, an applicant must choose to apply for either a full or a conditional release (release with controls). If an applicant applies for a full release, but ERMA New Zealand would like to impose controls, ERMA New Zealand would have to decline the full release application and suggest the applicant reapply for a conditional release. Issues such as this should be resolved at the pre-application stage. If an applicant chooses to apply for a conditional release, they must specify the controls, but it does leave ERMA New Zealand with the option of imposing additional controls if they see fit. Two conditional release applications for IBCAs have been submitted and approved since the 2003 HSNO Act amendment, essentially limiting the approval to IBCAs from a defined geographical area (biotype), consistent with those used in host specificity testing. Further details about conditional releases can be found on the ERMA New Zealand website (ERMA New Zealand 2007).

Decision maker

The Authority makes the decisions on whether to approve import into containment and/or release of

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the proposed IBCA. In accordance with the HSNO Act, members of the decision-making Authority represent a balanced mix of knowledge and experience. Currently the Authority is composed of five scientists, one Maori business specialist, one environmental lawyer and one Chair.

Data requirements

Information requirements to import into containment. Information that needs to be provided in an application for approval of import into containment includes details of the applicant, the purpose of the application, the identity of the organism to be imported, information on the biology and ecology of the organism, a description of the proposed containment system (physical and operational) and the ability of the organism(s) to escape from this system. Finally, the risks, costs and benefits of importing the agent into containment must be identified and assessed.

Information required for full or conditional release. Applicants are required to develop a full environmental risk, cost and benefit assessment by identifying and analyzing all possible hazards, risks, costs and benefits associated with the release of the organism. Host range assessment is usually central to the risk analysis. The more significant the effect, the more information is required. Organisms that present a greater potential risk will require more detailed information and assessment. Below is a brief outline of how risks, cost and benefits must be analyzed.

Identifying and assessing risks, benefits and costs: Identifying the relevant risks, costs and benefits involves looking at all the ways the biological control agent can affect people, communities and the natural environment, such as:

- risks to the life-supporting capacity of air, water, soil and ecosystems;
- the ability of people and communities to provide for their economic well-being, their social and cultural well-being, and the reasonably foreseeable needs of future generations;
- the sustainability of all native and valued introduced flora and fauna and the inherent value of ecosystems;
- public health;
- the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga;
- the economic and other benefits and costs arising from the use of a particular hazardous substance or new organism;
- New Zealand's international obligations.

Each risk needs to be understood in terms of the combination of magnitude of effect(s) and the likelihood of those effects occurring (Barratt and Moeed 2005). Risks should then be placed into broad categories to determine how much attention they need to be given. It is the applicant's responsibility to provide evidence that a structured and systematic approach has been taken to identifying risks, costs and benefits associated with the application. ERMA New Zealand has produced a concise guide to help applicants with the process of conducting analyses. This is available on their website (ERMA New Zealand 2007). In addition, they have compiled a comprehensive information sheet entitled 'Estimating the Beneficial Effects of Biocontrol Agents', detailing the main criteria that an applicant might address when assessing the magnitude and likelihood of the beneficial effects of their proposed IBCA. Suggested issues relate to the IBCA's efficacy, increased farming productivity, reduced cost of control and benefits to conservation. This information sheet can also be downloaded from the ERMA New Zealand website.

Fees

The full ecological risk, cost and benefit analysis of biological control releases that ERMA New Zealand operates comes at a relatively high cost, reflected in the fees for applications:

	New Zealand $
Notified (full release)	33 750 (approx. 17 000 euros)
Notified (conditional release)	Negotiated
Notified (containment)	11 250 (approx. 5700 euros)
Non-notified (containment)	2250 (approx. 1115 euros)
Statutory determination on grounds of reassessment	562.50 (approx. 285 euros)

Time frame

Under the HSNO Act, ERMA New Zealand has up to 100 working days (if a time waiver has not been agreed) to process a publicly notified application and inform the applicant of the decision made by the Authority. The timing depends largely on the quality of the application. For an application that does not need to be publicly notified, (i.e. approval to import into containment), ERMA New Zealand has up to 60 working days to process the application and inform the applicant of the decision made by the Authority.

Availability of information about regulation process to aid applicants

ERMA New Zealand has developed an extremely detailed and informative website around which it is easy to navigate (ERMA New Zealand 2007). It provides all necessary information needed to make an application and offers many helpful documents including application forms and guides for applicants that can be downloaded. Full text of all applications, evaluation and review reports and decisions for all applications are also available. In addition, a new information resource website has just been launched to provide specific assistance for biological control researchers and practitioners preparing an application to ERMA New Zealand to import a new biological control agent (Barratt et al. 2007) .

Public participation

A cornerstone of the HSNO Act is the public's right to know and be heard with regard to notified applications (those that may affect the environment in some way). New Zealanders are able to have their say and talk directly to the Authority. Import for release or release from containment of any new organism must be publicly notified. Applications that are exempt from being publicly notified and from public hearings may include those to import organisms into containment.

A notified application is one that is categorized as having significant public interest. Receipt of such applications must be 'publicly notified', in which case a 30 working day submission period is open to all members of the public. Public notification involves a summary statement being advertised through an alert in the major daily newspapers, on the ERMA New Zealand website, in 'The Bulletin' and by directly notifying people who have indicated that they wish to be advised of particular types of applications. A public hearing of an application would be held if the applicant or any of the submitters request it, or if ERMA New Zealand considers it necessary.

Length of validity of approvals

Approval to import into containment. There is no time limit for this type of approval.

Approval for full or conditional release. Once an organism is fully released into the environment, it is no longer considered a new organism and is thus no longer subject to HSNO Act regulation. The approval, therefore, has no validity time limit. However, if the organism is not released within 5 years, the approval will lapse, unless extended by the Authority. The exception to this rule is for organisms that are granted conditional release. In these cases, the approval may expressly state that it does not expire or an expiration date may be specified. If neither is stated, the approval will expire 5 years after the date approval was granted, unless the Authority explicitly states otherwise.

Is there a 'safe list' of IBCAs that are exempt from regulation?

The only circumstance under which the complete application process is not necessary is if the organism to be imported is not a 'new organism'. The HSNO Act defines a new organism as any species that was not present in New Zealand immediately before the date the HSNO Act came into effect (July 1998). ERMA New Zealand maintains a statutory register of organisms it has approved for importation for release or release from containment (available on their website; ERMA New Zealand 2007). If the organism of interest features on this register, then HSNO Act requirements are satisfied and the only remaining requirement is that MAF's biosecurity controls are met. If the organism does not appear on the register, but is already in New Zealand, then it is possible to obtain a determination from the Authority under the HSNO Act that it was indeed present in New Zealand when the HSNO Act commenced (Please refer to table 2 for a summary of the New Zealand regulatory system and its comparison to procedures in Australia, Canada and the USA).

Canada

3.3.1 Legislation and administration

The Canadian Plant Protection Act (1990) was enacted to prevent the importation, exportation and spread of pests injurious to plants. This Act was preceded by a series of Acts and Regulations going back to the Destructive Insect and Pest Act of 1910. According to the Act, a pest is defined as 'any thing that is injurious or potentially injurious, whether directly or indirectly, to plants or to products or by-products of plants, and includes any plant prescribed as a pest'. 'Beneficial' exotic biological control agents of weeds and invertebrates are considered potentially injurious to plants and thus fall under the same Act as plant pests. The Plant Health Division of the Canadian Food Inspection Agency (CFIA-PHD) administers the Act, a process that is overseen by the Minister of Agriculture and Agri-Food Canada (AAFC). The process for review of new introductions

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is the same for phytophagous and entomophagous IBCAs, i.e. IBCAs of weed and invertebrate pests respectively.

Application procedure

An applicant wishing to import and release a phytophagous or entomophagous IBCA must apply for:

- a permit to import the biological agent for scientific research purposes;
- release approval;
- a permit to import the agent for its release.

Permit to import for scientific research. An applicant wishing to import their potential IBCA to Canada to conduct research, such as host specificity testing, must submit an application for a permit to import (for scientific research) to the CFIA-PHD Import Office. Once all required information has been received CFIA-PHD will review the permit application form and, if satisfied, will recommend that CFIA issue a permit to import. These potential agents can only be used in containment and release from containment into the environment requires a further review process and authorization of the Director of the PHD.

Release approval. A petition for release of foreign arthropods into Canada must be submitted to the CFIA Import Office. Application forms must be accompanied with detailed information requirements as outlined in the North American Plant Protection Organisation (NAPPO) Standards (Regional Standards for Phytosanitary Measures) RSPM 12 (Entomophagous) and RSPM 7 (Phytophagous) (NAPPO 2000, 2001)). No release will be permitted without submission of the information requirements in the approved NAPPO format.

Permit to import for release. If release is granted based on the process outlined in fig. 3, either the conditions of the original permit will be amended to allow release or a new permit will be issued authorizing the release. Once approved, the conditions for import and release will usually be the same for all regions of Canada. However, certain provinces may have legislation that requires their prior agreement for release in addition to federal approval. CFIA endeavour to include representatives from these provinces on the Biological Control Review Committee (BCRC).

If approval is granted, the organisms are imported through a CFIA-certified containment facility, where their identity and health (vigour and disease-free status) are checked prior to their release into the environment. The CFIA prefers that imported organisms are not released directly into the field and that the F_1 or later generations will be released as an additional safeguard against disease and parasitism.

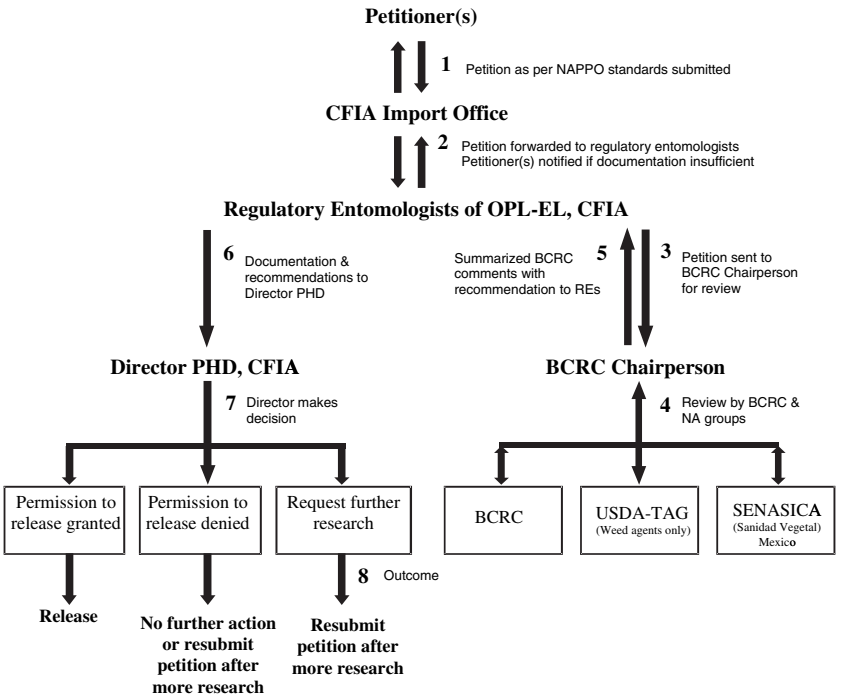

Fig. 3 Canadian review process for petitions for 'first time' import and release of entomophagous and phytophagous biological control organisms (from De Clerck-Floate et al. 2006). BCRC, Biological Control Review Committee; CFIA, Canadian Food Inspection Agency; NA, North American; OPL-EL, Ontario Plant Laboratory-Entomology Laboratory; PHD, Plant Health Division; USDA-TAG, United States Department of Agriculture-Technical Advisory Group; SENASICA, Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentara

Authoritatively identified voucher specimens must be deposited in the Canadian National Collection of Insects, Arachnids and Nematodes (CNC) in advance of release.

Decision-making process

An overview of the decision-making procedure in Canada for 'first-time' introductions of non-indigenous IBCAs is shown in fig. 3.

Permit to import for scientific research. Once all the required information has been received, CFIA-PHD will review the permit application form and, if satisfied, will recommend that CFIA issue a permit to import. The IBCA can then be transferred into a Canadian CFIA-authorized containment facility in order to carry out biological studies, such as host specificity testing. Conditions will be specified on the permit denying permission to release the agent into the environment.

Release approval. The Import Office forwards petitions for release to the regulatory entomologists of the CFIA's Ontario Plant Laboratory, Entomology Laboratory (OPL, EL). The regulatory entomologists will inspect the documentation and request notification of the petitioner(s) via the Import Office if documentation is incomplete or not formatted correctly according to NAPPO Standards. If the petition is incomplete, the applicant must resubmit with appropriate corrections and additions. Once the petition meets the necessary requirements, it is forwarded to the Chairperson of the BCRC for review.

The BCRC is coordinated by the research branch of AAFC. The Committee is mainly composed of taxonomists in entomology and botany, ecologists, scientists and/or specialists within the federal and provincial governments and Canadian universities. There is also Committee representation from Environment Canada (EC) and Health Canada's Pest Management Regulatory Agency (PMRA). The BCRC conducts a peer-review of the petitions. The expertise required on the Committee for each petition is determined on a case-by-case basis by the BCRC Chairperson and secretary. The Chairperson forwards the petition and a reviewer's comment sheet to the appropriate BCRC members, with a review due date. Members are required to rate the quality of the information provided and the science conducted by the petitioner on various aspects of the biological control agent's taxonomy, biology, efficacy, host range and impacts on non-targets. Each reviewer will provide an overall recommendation, i.e. release without reservations, release with reservations or not recommended for release. Phytophagous agent petitions are also circulated to SENASICA-Sanidad Vegetal (Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentara) in Mexico and the United States Department of Agriculture's Technical Advisory Group (USDA-TAG). Entomophagous petitions are only sent to SENASICA-Sanidad Vegetal; the USDA does not formally review release petitions for entomophagous agents under their legislation. CFIA-PHD does not approve releases without comment from TAG, though it is not obliged to follow their recommendations. However, biological control could have impacts on the entire continent and it is important to have a consensus for releases amongst all three regulatory bodies [SENASICA-Sanidad-Vegetal, USDA-Animal and Plant Health Inspection Service (APHIS) and CFIA-PHD].

Comments from the BCRC members are collated and analyzed by the Chairperson who may then request further information from the petitioner or clarification if the safety of the introduction is questioned. The Chairperson then summarizes all the comments received, with any additional information, and makes a recommendation to the regulatory entomologists of the OPL, EL on whether importation and release of the candidate agent in Canada should be allowed.

The regulatory entomologists then review all information and forward the BCRC recommendation and all the comments as well as their recommendation to the Director of the PHD (CFIA-PHD). Based on the information, the Director of CFIA-PHD advises the petitioner by letter of one of the following decisions:

- *Authorization of the importation and release of the arthropod agent.*
- *A request for more research on the agent.* A request for further research typically results in a resubmission of an amended petition for review.
- A decision to deny the release of the biological control organism in Canada. If release is denied, there need not be any further action. As reasons for the denial will be provided, in some cases the petitioner can opt to conduct further research and resubmit the petition at a later date.

Upon request, a copy of all comments may be provided to the petitioner(s), though CFIA reserve the right to protect the anonymity of the reviewers.

Import permit for release. Decisions of whether to issue an import permit for release purposes are made

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within the CFIA Import Office and are based largely on whether prior approval for release has been given, that quarantine facilities where the agent will be shipped to are CFIA-approved and that identity and health checks will be made before the agent is released into the environment.

If approved, it is recommended that importation be from the same population as those tested in the original screening reports. This will help prevent against introducing new biotypes or sibling species in taxonomically difficult groups. Even if researchers wish to re-introduce an already established biological control organism, it must be collected from the same region as the original population. Vouchers must be deposited in the CNC even for a re-introduction. The conditions on the permit will instruct the importer as to the port of entry, the containment facility where the species identity will be verified and vouchers removed, and where the agent can be released, treatment of host material and packing and post-release monitoring.

Decision maker

The Director of CFIA-PHD makes the final decision of whether or not to approve an introduction of an IBCA. Decisions are based on the recommendations of the BCRC, regulatory entomologists (OPL-EL) and in the case of phytophagous agents, TAG (USDA).

Data requirements

Information required to import for scientific research. Information that must accompany applications for importation of IBCAs includes a description of the agent being imported, its common name and scientific name (genus and species), a description of the purpose of importation as well as precautions that will be taken to prevent the spread of a pest. Various administrative details, such as the process and destination of the shipment, are also required.

Information requirements for release approval. Petitions for the release of an IBCA must contain host specificity and other biological data on the agent to be imported and released in a format and substance that conforms to the NAPPO standards for the release of exotic entomophagous and phytophagous biological control agents (NAPPO 2000, 2001). Below is an outline of the NAPPO requirements.

Proposed action: Here there is a requirement to specify the need for release, the reasons for IBCA choice as well as quarantine and release procedures.

Target pest/weed information: Information on aspects of biology, regulatory status, distribution, economic impact and benefits, related species in the proposed area of introduction, key published and unpublished scientific records as well as any organisms previously introduced or indigenous to North America that are known to attack pests must be provided. The pest's status in the USA must be stated if it is a joint petition between the USA and Canada or if there is shared concern in control of the pest.

Biological control agent information: Aspects of biology, source of agent population tested for release, geographical range, known host range, quarantine procedures for the IBCA, closely related genera or species in North America, history of past use as well as key published and unpublished scientific records must be provided.

Host specificity testing: Currently, the NAPPO guidelines for the release of entomophagous IBCAs do not list host specificity testing as a requirement prior to submitting a petition. However, determination of host range forms a central element in the benefit, risk and cost evaluation process, which is required for specifying the environmental and economic impacts of a proposed release (next criteria). In Canada, a petitioner can expect CFIA to suggest that some testing of candidate entomophagous agents be done, not only using indigenous arthropods as potential hosts but also using arthropods that have been previously released for the biological control of weeds, particularly if they are taxonomically close to the target host and occur in areas where releases are being proposed. It is recommended to follow the methodology for risk assessment as proposed by van Lenteren et al. (2006). This methodology integrates information on the potential of an agent to establish, its abilities to disperse, its host range (determined from laboratory and field tests) and its predicted direct and indirect effects on non-targets.

Environmental and economic impacts of the proposed release: Impact on vertebrates (including humans), direct impacts on target and non-targets, indirect effects on species that depend on target or non-target species and possible effects on the physical environment and on threatened/endangered species. It is the petition reviewer's duty to weigh the benefit, risk and cost of a release against the benefits, risks and costs of other pest control choices.

Plans for post-release monitoring: Again, the NAPPO standards for the release of entomophagous IBCAs do not specify post-release monitoring plans as a requirement. However, a petitioner can expect

CFIA to request that they fulfil the same requirements that are outlined in the standards for the release of phytophagous IBCAs. Here it states that researchers and practitioners must demonstrate that a plan is in place to study economic and environmental impacts of programmes after the release of an agent to assist in assessing programme impacts and to validate and improve methods of release or host specificity testing. The plan should include information regarding:

- the agent's establishment, increase and spread;
- the incidence and level of direct attack on the target pest and on non-target organisms;
- changes in target and attacked non-target growth, reproduction, survival and various population parameters;
- changes in community-level processes and structure.

Import permit for release. Information required for approval for release includes details of the importer and exporter, a listing of all the destinations receiving the imported material, its place of entry into Canada, means of transportation, reasons for importation and a detailed description of the material. All material must pass through a CFIA-approved quarantine facility to enable various checks to be carried out to confirm the identity of the agent as well as its health and disease-free status.

Fees

Fees charged in Canada are as follows:

$15 (approx. 10 Euros): Applications/permits for scientific research purposes.

$35 (approx. 24 Euros): Applications/permits for purposes other than research.

$10 (approx. 7 Euros): Amendment to a permit.

Time frame

Once all the information has been received (petition, recommendations of BCRC, TAG and regulatory entomologists) and the CFIA-PHD has completed a review of the permit application form, the CFIA will endeavour to issue a decision on permit to import within five to ten working days. For a new introduction (release), the total time from receipt of petition to issuance of a permit may take up to 6 months.

Availability of information about regulation process to aid applicants

The permit application form for import, together with information regarding import requirements, are displayed on the CFIA website (CFIA 2007). The NAPPO Standards are also available on the Internet (NAPPO 2000, 2001). Although there are no specific guidelines for the whole process, AAFC and the CFIA have produced a comprehensive guide to provide petitioners, reviewers of petitions and interested Canadian citizens with information on the procedure (De Clerck-Floate et al. 2006).

Public participation

There is currently no public involvement in the review process. Public participation is recognized as a necessary step in the evolution of the review process, yet it is unclear as to how it could be incorporated into the current system. The regulators are always looking for input to the review process from knowledgeable people.

Length of validity of the permits

Both permits to import IBCAs (for scientific research and for release) are valid for a period of 3 years unless otherwise stated. All permits are renewable after expiry and are valid for multiple shipments and unlimited quantities unless otherwise stated. Permits issued to individuals doing their own collecting (i.e. importer and exporter are the same person) are valid for 1 year. Researchers are permitted to hand carry live insects into Canada under permit if they proceed immediately to an approved containment facility.

Is there a 'safe list' of IBCAs that are exempt from regulation?

There are currently about 60 arthropod biological control agents that have been historically used in commercial situations in Canada. Due to their safe record of use, and if imported from CFIA-approved sources, they do not have to undergo the petition process prior to importation. The names of these agents can be obtained on request. The most important questions for regulators to consider are source of the import, species, destination and end use. The Permit Section of the PHD may request voucher specimens in advance of approving the import of a historically approved species from a new country or source. However, all non-indigenous organisms for entomophagous and phytophagous classical biological control must be reviewed through the petition process. (Please refer to table 2 for a summary of the Canadian regulatory system and its comparison to procedures in Australia, New Zealand and the USA).

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United States of America

Phytophagous invertebrate biological control agents

Legislation and administration

The import and release of exotic weed IBCAs fall under the new Plant Protection Act of 2000. The Plant Protection and Quarantine of the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS-PPQ) administers this Act, overseen by the Secretary of Agriculture. The Plant Protection Act provides APHIS-PPQ authority to regulate 'any enemy, antagonist or competitor used to control a plant pest or noxious weed'. Biological control organisms are broadly defined by this statement and are thus subject to regulation under this Act. The National Environmental Policy Act (1969) (NEPA) and the Endangered Species Act (1973) (ESA) also affects the decision to release a non-indigenous weed IBCA into the environment. APHIS-PPQ is assisted in its regulatory responsibility for issuing import and release permits for weed IBCAs by TAG.

Technical Advisory Group for biological control agents of weeds. TAG is an independent voluntary committee that has been operating since 1987. Prior to this, the group existed on a smaller scale under the name of the Subcommittee on Biological Control of Weeds. This group was initially established in 1957, changing its name to the Working Group in 1971 and then being replaced by TAG in 1987. Since then, TAG membership has had to comply with the Federal Advisory Committee Act of 1972. TAG is made up of 13 federal agencies that support, conduct research on, or use weed biological control as part of their activities. This interagency group was established to provide a science-based link between the research community and the regulatory agencies involved in weed biological control. Primarily they advise weed biological control researchers and provide the APHIS-PPQ permit unit with a recommendation on the proposed action of the applicants. TAG functions under APHIS-PPQ procedures and is facilitated by an executive secretary from APHIS-PPQ who is not a voting member. The TAG Chair is elected by its members for a 3-year, renewable term. Membership is indefinite until members retire or their agencies name someone else. Core groups represented on TAG include:

- five USDA agencies;
- six US Department of Interior (USDI) agencies;
- US Environmental Protection Agency (EPA);
- Department of Defense;
- representatives from Canada and Mexico.

Other groups or agencies may also be co-opted if specific expertise is required.

TAG has no legal mandates or powers and does not make final decisions about whether an agent should be approved for import and release in the USA. It only recommends to APHIS-PPQ that an agent be approved or denied and recommends specific action to petitioners before they apply for a permit. However, the recommendations of TAG are normally followed. The advisory role of TAG members to APHIS-PPQ covers:

- incorporating member agencies' concerns and perspectives into planning biological control programmes;
- reviewing petitions and assessing the risks and benefits associated with each one, with the aim of making conservative recommendations to APHIS-PPQ;
- recommending specific actions for the petitioner before a release application is written to APHIS-PPQ;
- assisting in defining a course of action when there might be a conflict of interest.

Application procedure

The application procedure in place in the USA is a lengthy one and each step can seem quite complex. An overview of the process is displayed in fig. 4. In order for a petitioner to gain approval for the import and release of a candidate weed IBCA, they must apply for the following:

- approval of a test plant list;
- permit to import agent into containment;
- permit to release agent into the environment;
- interstate movement of approved weed IBCAs (if necessary).

Below is an outline of what an applicant might expect to experience during each step of the application process. A summary of this process is also depicted in fig. 4.

Approval of test plant list. The first step in the procedure for applying to import a weed IBCA is to contact TAG and submit a proposed test plant list. At this early stage of the approval process, TAG will make recommendations on the target weed choice and comment on the proposed test plant list for host specificity testing. It is also recommended at this stage to contact the Departments of Interior and Commerce to be sure that threatened and endangered species are considered in the test plant list. The appropriate agency is usually the U.S. Fish and

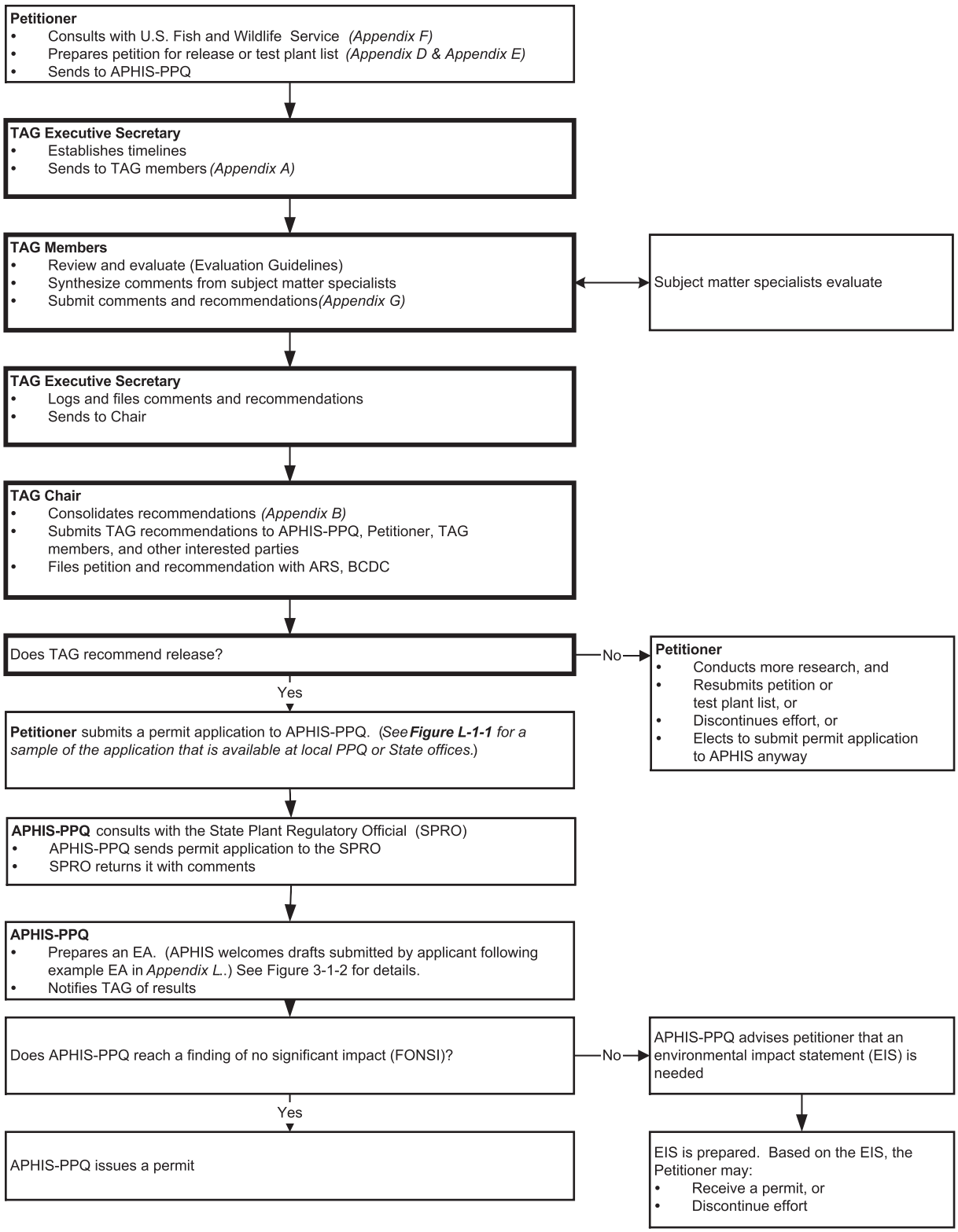

Fig. 4. The procedure for the review of applications to import and release weed biological control agents in the USA [from TAG Reviewer's Manual (USDA, 2007)]. Not shown in this figure is the recent requirement for review of dossiers by Canada (Canadian Food Inspection Agency, Plant Health Division) and Mexico (SENASICA (Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentara) - Sanidad Vegetal). APHIS-PPQ, Animal and Plant Health Inspection Service of Plant Protection and Quarantine; ARS, BCDC, Agricultural Research Service, Biological Control Documentation Centre; EA, environmental assessment; FONSI, finding of no significant impact; TAG, Technical Advisory Group

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Wildlife Service (FWS), within the Department of Interior. Depending on the nature of the proposed action, it may also be necessary to consult the National Marine Fisheries Service (NMFS), within the Department of Commerce. In practice, a consultation with NMFS is rarely necessary. Both these agencies have the responsibility of administering the ESA. Receiving input on a weed biological control project at an early stage from the TAG and Departments of Interior and Commerce can disclose problems or concerns that permit applicants can address at an early stage, potentially saving years of delays.

Permit to import agent into containment. To import a potential weed biological control organism into the USA for host specificity testing, a permit application (PPQ form 526) must be submitted to APHIS-PPQ. Approved biological control agents can then be imported, but only into an adequate high-security containment facility in the USA.

Permit to release agent into the environment. The process of applying for a permit to release a candidate weed IBCA is the most complex, involving several different steps. Outlined below are the various procedures an applicant must follow.

Submit petition for release to TAG: After host specificity testing has been completed, a petition for release of the biological control agent must first be submitted to the TAG executive secretary for recommendation. All proposed first-time releases of non-indigenous weed IBCAs must be reviewed and recommended by TAG.

Submit petition for release to APHIS-PPQ: When a recommendation for the release of the weed biological control organism is received from TAG, it is then necessary to submit an application (PPQ form 526) requesting the environmental release of the biological control agent to APHIS-PPQ.

USDA requires a separate application for every state in which biological control agents are to be sent. Prior to issuance, USDA generally consults with the state agricultural officials in the state of destination.

Submit additional documents; environmental assessment (EA) and biological assessment (BA): The act of releasing biological control organisms is considered a federal action and thus two additional documents must be produced in order to comply with the NEPA and the ESA. Although APHIS-PPQ is ultimately responsible for compliance with those environmental statutes, the applicant can lessen the turnaround time by preparing and submitting draft documents for APHIS-PPQ to finalize. The document required for NEPA compliance is the EA, a concise public document (of around 15 pages) that provides sufficient evidence and analysis to determine whether a finding of no significant impact (FONSI) can be reached or whether an environmental impact statement (EIS) must be prepared. The EA provides the public with the potential positive and negative environmental impacts that may occur as a result of the release of a non-indigenous biological control organism into the environment. The document required for compliance with the ESA is the BA. This document is usually submitted to the FWS as part of the consultation process (this is conducted independently of FWS's role on TAG). Specific requirements of the EA and BA are outlined in the 'Data requirements' section below.

Consult with FWS: According to the ESA, any action that is authorized, funded or carried out by a federal agency must comply with the consultation requirements of the ESA. This compliance may be achieved through formal or informal consultation with FWS or NMFS. Informal consultation involves the submission of the BA to FWS and/or NMFS for concurrence with a determination that the release of the biological control organism 'is not likely to adversely affect endangered or threatened species or their habitats'. Formal consultation is required when there are concerns that the proposed release may adversely affect endangered or threatened species or designated critical habitat. APHIS-PPQ will determine whether formal consultation with those agencies must be conducted at this point in the process. For weed biological control releases, both formal and informal consultations are conducted between FWS and/or NMFS and APHIS. However, applicants from any federal agency may conduct the consultation. Non-federal applicants may conduct informal consultations but first must be designated as a non-federal representative by APHIS-PPQ.

APHIS-PPQ completion of EA, notification of public, decision: Once the consultation is complete, APHIS-PPQ incorporates the response from FWS and/or NMFS (either Letter of Concurrence or Biological Opinion) into the EA and makes any final changes necessary. The USDA Office of General Counsel (OGC) reviews the EA to be sure it meets all legal standards. Once the EA has been approved by the OGC, APHIS-PPQ publishes a 30-day notice of availability of the EA in the federal register to allow for public comment on the proposed action. After considering the comments and consulting with the relevant state plant regulatory official, APHIS-PPQ either:

- reaches a FONSI (the desired outcome) and issues the release permit;

- advises the applicant that an EIS must be prepared (a document prepared in compliance with NEPA when significant impacts are expected from the proposed action); or
- advises the applicant to discontinue the project.

Interstate movement of approved weed IBCAs. Interstate movements of all arthropod weed IBCAs must be authorized by an APHIS-PPQ permit. However, permits for environmental release will only be approved for states that have been covered under an EA and consultation with FWS and/or NMFS. A supplemental EA and another consultation must be conducted before releases into any additional states can be approved by APHIS-PPQ. Supplemental approvals can certainly take some time to obtain, although they are generally not as time consuming as the original approval process. However, applicants are encouraged to consider broad areas for release when preparing the TAG release petition and environmental documentation for initial approval.

Decision-making process

Figure 4 shows an overview of the decision-making process for IBCA introduction and release in the USA.

Approval of test plant list. TAG review: When reviewing a test plant list, TAG members treat it as if it were a petition. Guidelines for reviewing test plant lists are provided in the TAG Reviewer's Manual and use a strategy based on Wapshere (1974). At this early stage of the approval process, TAG reviewers make comments on the target weed choice and formulate any recommendations for the proposed test plant list for host specificity testing. Their comments and recommendations are recorded on a reviewer's comment sheet for test plant lists.

Permit to import agent into containment. APHIS-PPQ makes the final decision to approve an application for import of a biological control agent based on information provided by the applicant on the PPQ form 526.

Permit to release agent into the environment. TAG review: TAG reviewers are provided with a set of guidelines in the manual to refer to when reviewing and evaluating petitions for environmental release of a biological control agent. The guidelines are intended to act as a checklist to ascertain how much of the information has been addressed by the applicant and how thoroughly each topic was covered in the petition. Reviewers record their comments on a reviewer's comment sheet and then develop an overall evaluation and recommendation concerning the proposed action from their agency's perspective. All TAG members are expected to fully understand their agency's perspective on biological control activities. Petitions received by TAG are also sent to SENASICA-Sanidad Vegetal in Mexico and CFIA-PHD in Canada for review before recommendations are given to APHIS-PPQ.

APHIS-PPQ decision: The final decision to approve an application for import of a biological control agent is based on information provided in the petition, the EA and also the BA. The recommendations from TAG are very influential of the final decision. Comments from relevant departments, such as FWS and NMFS, and from the public are also considered. In certain cases, APHIS is able to issue a permit for the environmental release of a biological control agent that contains certain provisions or requirements concerning release procedures, post-release monitoring or mitigation measures.

Interstate movement of approved weed IBCAs. Approvals for releases into any additional states not included on the original release permit will be approved by APHIS-PPQ based on the supplemental EA and on the provisory that another consultation is conducted with FWS and/or NMFS and that their recommendations are positive.

Decision maker

Ultimately, APHIS-PPQ makes the final decision of whether to approve the import, environmental release and interstate movement of a weed IBCA.

Data requirements

The TAG Reviewer's Manual specifies all the data requirements for the test plant list and biological control agent release applications. Below is an outline of the suggested requirements:

Information required for approval of test plant list. An introduction outlining the nature of problem and proposed action must first be given. Also required is target weed information including taxonomy, description, distribution of target weed, taxonomically related plants, life history, impacts, alternative management options and known host range of candidate biological control agent. Finally, the test plant list must be supplied.

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Information requirements for permit to import agent into containment. An application to import an agent involves the submission of a PPQ form 526 to APHIS-PPQ. Information to be specified on this form includes the scientific name of the organism as well as its major hosts. Details regarding where the material is to be shipped from and to what state it will be shipped is also required. The containment specifications should be defined, including a description of the facility in which they will be kept and the cages, screening and measures that will be taken to prevent escape during rearing, cleaning, transfer and disposal of the insects. A new NAPPO standard recommends that a certificate of purity/identity from the appropriate government agency in the country of origin must also accompany the shipments (NAPPO 2006).

Information needed for permit to release agent into the environment. TAG petition: The same information that was provided when the test plant list was submitted must be given again at this stage. Additional requirements include information related to the biological control agent such as its taxonomy, geographical range, life history and population data. Supporting documentation must be provided containing host specificity and other biological data on the agent to be imported and released in a format and content that conforms to the NAPPO standards for the release of exotic phytophagous biological control agents (NAPPO 2001) (see 'Canada' section for more details about these guidelines). The test plant list and explanations for its design and positive control need to be submitted as well as a protocol for releasing the agent and plans for post-release monitoring. In addition, any potential environmental impacts, human impacts, potential economic impacts, non-plant impacts, proposed methods for mitigation, abiotic and edaphic effects and outcomes of no action must all be addressed in a discussion. Finally the petitioner must provide his/her own conclusion.

Environmental assessment: The EA is a public document that must be written in a non-scientific format and provide descriptions of the purpose and need for the proposed action, the alternatives (including no action) and the affected environment. Host specificity data need to be provided together with a list of the threatened and endangered species in the infested and surrounding area, a description of environmental consequences of releasing the biological control agent and consequences of taking no action (including effects on non-target organisms and threatened and/or endangered species), the consequences of an unsuccessful control attempt and any potential irreversible effects of the control strategy.

Biological assessment: The BA should address several issues including descriptions of the action to be considered, the specific area that may be affected by the action, any listed threatened and endangered species or critical habitat that may be affected by the action, the manner in which the action may affect any listed species or critical habitat as well as an analysis of any cumulative effects. Relevant reports, including any EIS or EA, must be provided as well as any other relevant available information on the action, the affected listed species or critical habitat.

Interstate movement of approved weed IBCAs. The requirement in order to gain approval to move weed IBCAs between states comprises a supplementary EA, the contents of which are outlined above.

Fees

USDA does not charge a fee for plant pest permits. User fees may be imposed in future.

Time frame

To import a potential weed biological control organism into the USA for host specificity testing, it takes 4–6 weeks from submission of the application to receive a permit.

In terms of release applications, the more complete the EA and BA documents are upon submission to APHIS-PPQ, the faster the review process is likely to be. TAG members are allowed 6 weeks to review and evaluate petitions. In practice, the full approval process takes approximately 18 months.

Availability of information about regulation process to aid applicants

There is some helpful information on the APHIS website (APHIS 2007). USDA has also compiled a manual detailing guidelines for evaluating the safety of candidate phytophagous IBCAs. The purpose of the manual is primarily to provide comprehensive information and guidelines to TAG reviewers but it also serves as a source of information to practitioners and researchers (USDA 2007).

Public participation

APHIS-PPQ publishes a 30-day notice of availability of the EA in the federal register to allow the public to comment on the proposed action.

Length of validity of the release permit
USDA issues permits for up to 3 years. However, under certain circumstances, the validity period may be different.

Is there a 'safe list' of IBCAs that are exempt from regulation?
The US government does not hold such a list. However, there is a 'safe list' of 'APHIS-permitted beneficials imported into the USA from other countries', which includes weed IBCAs. The list is available on the Association of Natural Biocontrol Producers (ANBP) website (ANBP 2007).

Entomophagous invertebrate biological control agents

Legislation and administration
The USA currently has no comprehensive regulatory framework for importing and releasing exotic entomophagous IBCAs (Messing 2005). The nominal controlling agency, APHIS-PPQ, USDA, has statutory authority to regulate plant pests. There is a fairly well-defined system to screen exotic herbivorous biological control agents of weeds that have the potential to feed on desirable plants (see previous section) (Messing and Wright 2006), but the situation for entomophagous IBCAs lags far behind. In 2000, the new Plant Protection Act came into operation allowing APHIS-PPQ authority to regulate organisms that may directly or indirectly harm plants or plant products. Unlike the previous Federal Plant Pest Act of 1957, the Plant Protection Act broadly defines biological control agents and recognizes their potential to control plant pests and thus under this Act, biological control organisms became subject to regulation. APHIS-PPQ is authorized to regulate importation, interstate movement and environmental release of biological control agents but may deregulate the interstate movement and environmental release of agents that APHIS has determined not to be plant pests.

Within the past decade, APHIS has made a few attempts to establish regulations specific to the importation of entomophagous IBCAs. However, these new regulations are poorly understood and have been difficult to implement. The task of regulating biological control agent import and release has grown even more difficult since the terrorist attacks of 2001 due to the resulting bureaucratic reorganization of APHIS and the development of the new Department of Homeland Security (Messing 2005). Thus, the current regulations for movement and release of entomophagous IBCAs outlined below are still those that were developed under the older Federal Plant Pest Act of 1957.

Application procedure
Applicants must complete an APHIS-PPQ application form (PPQ form 526) and obtain separate permits (required by APHIS-PPQ) for:

- importation to USA containment facilities;
- domestic movement to other containment facilities;
- release of organism to the environment.

No changes to these procedures are anticipated when new regulations are imposed under the Plant Protection Act (Mason et al. 2005).

Importation to USA containment facilities. Permits for importation into quarantine are issued to facilitate the removal of contaminants from foreign sources, to confirm the identity and purity of the agents and to develop documentation that can be used to support future applications for release to the environment. As the first step in the application process, a biological control practitioner must submit a PPQ form 526 in order to gain approval for the first import of their agent into containment.

Domestic movement to other containment facilities. A separate PPQ form 526 must be submitted and approved before a biological control practitioner may move their agent to another containment facility within the USA.

Release of organism into the environment. It is necessary for researchers to submit another application (PPQ form 526) to APHIS-PPQ for release approval for the organism into the environment. If the organism is non-indigenous and has not been released previously in the USA, then it is necessary to accompany the application with biological data specified in the NAPPO guidelines (NAPPO 2000).

Once applications have been received by APHIS-PPQ, the supporting documentation accompanying the applications is reviewed to decide whether the agent can be released into the environment safely. Recently APHIS instituted new rules regarding the removal of biological control organisms from quarantine, establishing a requirement for consultation and thorough review of dossiers by Canada and Mexico under the auspices of NAPPO (Messing 2005).

If it is decided that the agent may pose potential negative impacts on non-target species, especially endangered and threatened species, this triggers the

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ESA of 1973 and requires consultation with the FWS within the Department of Interior. In these cases, they will request submission of a BA to satisfy provisions of the ESA.

Applicants who are employees of a federal agency, have received any federal funds for the project, and/or have employed any federal workers are obliged to write and submit an EA as a requirement of the of 1972 NEPA. This document addresses both the positive and negative environmental impacts and those deemed to have higher risk are then required to prepare a more detailed EIS. Those of lower risk are issued a FONSI.

Currently not all applications require a formal EA. It is expected that this situation will soon change and that APHIS-PPQ will begin issuing permits for release of entomophagous agents with new regulations under the Plant Protection Act. This change will require APHIS-PPQ to develop formal EAs to document for the public record of information used to make the federal decision (Mason et al. 2005).

If APHIS-PPQ determines that the release of the agent will not likely result in adverse impacts to plants or non-target species, a determination of no jurisdiction is made, and the agent may be moved and released throughout the USA without an APHIS-PPQ permit. However, individual states may also require their own permits under state laws and regulations. Each state also has its own system to permit biological control agents, and state regulations can be more stringent than federal ones, such as those in place in Hawaii (Messing and Wright 2006).

It is also expected that APHIS-PPQ will begin requiring permits for the domestic movement of all entomophagous agents, except those deregulated by an official listing in the federal register. Listing will require an EA plus a continuing safety record following establishment in broad areas of the USA (Mason et al. 2005).

Laboratory-reared biological control agents imported for commercial purposes also require APHIS-PPQ permits when they have been commercially produced outside the USA, including Canada and Mexico. Furthermore, a separate permit application must be submitted for every state in which release of an organism is planned. State permits may also be required for releases in individual states. A new NAPPO standard recommends that a certificate of purity/identity from the appropriate government agency in the country of origin must also accompany the shipments (NAPPO 2006). Again, if the organism is non-indigenous and has not been released previously in the USA, then it is necessary to accompany the application with information conforming to the NAPPO guidelines.

Decision-making process

Importation to USA containment facilities. APHIS-PPQ makes the final decision to approve an application for import of a biological control agent based on information provided by the applicant on the PPQ form 526. Import permits will be issued with conditions specified relating to containment of the agent.

Domestic movement to other containment facilities. Again, APHIS-PPQ bases their decision on information provided by the applicant on the PPQ form 526. Permits for domestic movement will be issued with conditions specified.

Release of organism into the environment. APHIS-PPQ decisions of whether or not to issue permits to release agents into the environment are based on anticipated indirect/direct plant pest risks, including potential impacts on non-target species (especially those that are endangered and threatened). Information used to make these decisions include the petition, the EA and the BA. Comments from Canada and Mexico as well as relevant departments, such as FWS, and from the public are also considered.

Decision maker

Ultimately, APHIS-PPQ makes the final decision of whether to approve the import and environmental release of an entomophagous IBCA.

Data requirements

Information requirements for importation to USA containment facilities. As with weed biological control applications, a PPQ form 526 must be submitted to APHIS-PPQ. The information required includes the agent's scientific name and its major hosts. Details regarding the geographical origin of the material as well as its state during shipment are also required. The containment specifications should be defined, including a description of the facility in which they will be kept and the cages, screening and measures that will be taken to prevent escape during rearing, cleaning, transfer and disposal of the insects.

Information needed for domestic movement to other containment facilities. For these applications, another PPQ form 526 must be submitted containing the same information as described above.

Information required for release of organism into the environment. A PPQ form 526 must again be submitted as part of an application to release an organism into the environment together with supporting documentation about the organism to assist in making a risk assessment. This documentation must contain host specificity and other biological data on the agent to be imported and released in a format and content that conforms to the NAPPO standards for the release of exotic entomophagous IBCAs (NAPPO 2000). See 'Canada' section for more details about these guidelines.

For information regarding the requirements in each of the BA and EA, refer to the 'Data requirements' section in 'United States of America Weed Invertebrate Biological Control Agents'.

Fees

At present, USDA does not charge a fee for plant pest permits although user fees may be imposed in future.

Time frame

Currently no time limits are given to reviewers when applications are sent to them for review. In practice, approvals for release can take approximately 18 months.

Availability of information about regulation process to aid applicants

Information is scarce. There is some information regarding the import of biological control agents of arthropods on the APHIS website (APHIS 2007) although the information content is presently somewhat limited. The PPQ form 526, required by APHIS-PPQ, may be downloaded from their website.

Public participation

Currently, no public notification or participation is involved in the decision-making process for biological control agent import and release applications.

Length of validity of the release permit

USDA issues permits for up to 3 years. However, under certain circumstances, the validity period may be different.

Is there a 'safe list' of IBCAs that are exempt from regulation?

As with weed IBCAs, the US government does not hold such a list. However, there is a 'safe list' of 'APHIS-permitted beneficials imported into the USA from other countries', which includes IBCAs. The list is available on the ANBP website (ANBP 2007).

Table 2 shows a summary of the USA regulatory system and a comparison to procedures in Australia, New Zealand and Canada.

Discussion and Conclusions

There are several recommendations that can be given for a European IBCA regulatory system based on the systems in place in Australia, New Zealand, Canada and the USA. These countries have been implementing some form of IBCA regulation for at least 40 years. Their regulatory systems have also been evolving in complexity over the years and thus the components that help make them efficient and workable systems, as well as those that do not, are by now quite apparent. We recommend the following components could be adopted and incorporated into a workable regulatory framework for a much-needed harmonized IBCA regulatory system in Europe.

Legislation and administration

None of the four countries analyzed apply restrictions to the use of native IBCAs, except in New Zealand when the IBCA is a protected native species. As its first step, Europe should follow this lead and apply regulations only to exotic IBCAs, which can be described as 'not native to a particular country, ecosystem or ecoarea (applies to organisms intentionally or accidentally introduced as a result of human activities) [ISPM No. 3 1996]' (FAO 2006).

In all four countries, there exists a legislative system for the introduction and release of IBCAs, with at least one governmental body administering the process. Depending on the country, regulation of IBCAs is covered under different Acts including those pertaining to plant protection, biodiversity conservation, endangered species and environmental protection. Australia is the only country to have additional legislation that is specific to biological control (the Biological Control Act). In terms of administration, it varies between countries as to whether the Departments of Agriculture or the Environment are involved in the authorization of IBCA import and release. In Australia and New Zealand (at least in terms of IBCA import approval), both departments play a role.

It can be foreseen that regulation will be more complicated in Europe due to the fact that it comprises 46 countries, all with their own governments, legislative systems and border controls. In some respects, the situation can be likened to Canada and the USA, both composed of provinces and

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states, respectively, with their own provincial or state legislation and administration. In Canada, and for the most part in the USA, the regulatory process is administered at a federal level and NAPPO harmonizes the regulatory needs of the three contiguous North American countries (Canada, Mexico and the USA). A harmonized regulatory system for IBCAs across Europe would be difficult to manage without a similar central body to administer the process.

Therefore, based on these findings, it is our recommendation that a EU level governmental body administers the implementation of regulation in Europe. This body would not necessarily conduct the assessment of dossiers (see 'Application procedure' section), but its approval would be required for all exotic IBCA introductions. Whether or not an EU administrative body should be created solely for this purpose, or whether an existing one could be utilized, is an issue for debate and should be decided based on the existing structure of the EU government. This body would be composed of representatives from all European countries, thereby allowing any potential concerns to be raised from all parties. For example, one concern associated with European releases may be the ability of IBCAs to easily disperse across borders into neighbouring countries. A system in which release approval is granted by a European-level body would ensure the prior consent of neighbouring countries. Regarding the European countries that do not belong to the EU, it may be feasible for them to agree to abide by this regulatory system and so become 'associated' with the EU for this particular purpose.

As biological control projects nowadays also spark concerns about potential non-target effects in agricultural and non-agricultural ecosystems, Australia, New Zealand and the USA have seen the involvement of both agricultural and environmental government bodies in the regulatory processes for IBCA introductions. In order for a European regulatory system to remain streamlined, it is recommended that only one body be selected to administer the regulatory process in Europe, which is capable of incorporating both agricultural and environmental issues into the regulatory procedures.

Another matter for consideration is whether the proposed regulation should be implemented via legislation. Australia, New Zealand, Canada and the USA all have legislation in place covering the import and release of IBCAs and this has so far proved to be an effective method of regulating the use of IBCAs across each country. In order to succeed in achieving a harmonized regulatory system for IBCAs in Europe, we recommend that Europe follow suit as some form of legislation would be a powerful way of ensuring that each European country adheres to the same regulatory processes. However, it is vital that the necessary extra costs and administrative work be kept to a minimum so that applicants would not be faced with unmanageable fees and unreasonable dossier turnaround times (see sections on 'Fees' and 'Time frame').

Application procedure

In all four countries examined in this paper, approval for import into contained facilities must be sought if further experiments are to be conducted on the IBCA within the country into which it will potentially be released. A regulatory system that offers the opportunity to apply for a permit to import an agent into contained facilities is crucial for Europe. Certain species required for non-target assessment are not always present in the agent's country of origin. Moreover, natural genetic and physiological variations between those non-target species in the area of the agent's origin and its counterparts in the area of release could lead to discrepancies in behaviour and survival under experimental conditions and thus render the risk assessment data erroneous. For these reasons, the capacity to transport agents between European countries prior to their release is a necessity for the success of certain biological control programmes.

Prior to conducting risk assessments in Australia and the USA (for phytophagous IBCAs only in the USA), it is obligatory for the applicant to seek approval of their host specificity test list. Taking a slightly different approach in New Zealand, ERMA New Zealand encourages the applicant to liase with its Agency staff at an early stage of a biological control project so that the host specificity test list, among other issues to be addressed in the risk assessment, can be discussed. This early liaison has proved to be an important early step in biological control programmes in New Zealand, ensuring that the applicant has considered all the risks, costs and benefits associated with the potential introduction as well as the scientific and technical issues associated with the planned risk assessment studies. A system where initial host test list approval is obligatory could burden the researcher and may not be advantageous as host test lists will often have to be changed based on ongoing test results. However, a

regulatory system that offers pre-submission advice to applicants could be of high value in Europe, particularly for first-time applicants. As a result of such an advisory service, biological control programmes lacking potential may be terminated at an early stage, thus saving the applicant significant time and costs that may otherwise have been invested in the project. Moreover, these meetings would help to improve the standard of release applications, ensuring that they contain the necessary data upon first submission. Not only would this save the applicant valuable time, but also the time and costs invested by the administrative body would be curtailed. Overall, the efficiency of the review process would be improved and release approval for a biological control agent could potentially be granted in a much shorter period of time.

Regarding the question of who should assume responsibility for operating such a pre-submission advisory service, it is the natural assumption that the group responsible for conducting dossier reviews should also be available to proffer advice to applicants. In New Zealand for example, the Agency staff at ERMA New Zealand who liase with applicants at the start of a programme is the same staff who later assess the review applications. Depending on the decision made for Europe in terms of who should review the release applications, it is recommended that an advisory service be provided by this same group due to the experience and expertise they will possess in dealing with release applications.

Decision-making process

In terms of the dossier review process, this broadly operates in much the same way in Australia, Canada and the USA in that the dossiers are distributed to scientific experts within the country for independent review. In New Zealand, scientific experts are also often consulted or co-opted onto the review panel. Reviewers are a combination of university and government-affiliated scientists representing a broad range of expertise. The main difference between countries is that Canada and the USA both have a committee for the pure purpose of conducting these reviews. The BCRC and the TAG group are very effective for providing sound science-based reviews on biological control projects and the final decisions made by CFIA-PHD and APHIS-PPQ are highly influenced by their recommendations. Although there is no specific review committee in Australia, the opinions of the 21 scientific co-operators also play a significant role in the outcome of the IBCA release application as any concerns that a co-operator may have with a particular application have to be resolved between him/herself and the applicant before the application process can proceed. In New Zealand, the opinion of scientific experts consulted or co-opted onto the review panel is also central to the decision-making process.

The science-based independent review process has worked efficiently for the countries in which it operates. It is quite feasible that a similar system could be successfully implemented in Europe, with the creation of a panel of scientific experts (expert panel) to review dossiers. Members of the panel could be nominated to perform a review on a case-by-case basis depending on the nature of the dossier, but there should be the further possibility to seek an external review if additional expertise is required. It is vital that there would be representation from several European countries on the panel, not only to ensure a fair review process but also to increase the number of external contacts to which the panel has access when seeking additional scientific expertise. As discussed previously, this expert panel would also provide the pre-submission advisory service to applicants.

Decision maker

In all countries analyzed in this paper, the ultimate decision of whether a release application will be approved lies in the hands of an authority figure within the governmental body administering the regulatory process. However, in each country the final decision is heavily influenced by the opinions of the co-operators/scientific experts who review the applications. Thus, although one person (or more in New Zealand) ultimately makes the final ruling on the application, the decision embodies the views and opinions of a number of different scientists representing a broad range of expertise. The decision-making process is therefore fair and unbiased.

We propose that this system also be embraced by Europe. The decision reached by the expert panel would provide the EU administrative body with a recommendation of how to proceed. It would then lie in the hands of the European representatives on this EU administrative body to make the official ruling. If this system were to be adopted, then it would be of utmost importance that the European representatives on the administrative body are knowledgeable about the practice of biological control and recognize the value of the expert panel's recommendation.

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Data requirements

Europe has already made substantial progress in terms of devising guidelines to summarize the data requirements for dossier preparation (see table 1). The latest guidelines, resulting from the IOBC/WPRS Commission for the Harmonisation of Regulation of Invertebrate Biological Control Agents, entitled 'Guidelines on information requirements for import and release of invertebrate biological control agents in European countries' (Bigler et al. 2005b), are the most up-to-date comprehensive guidelines available in Europe. Provided that industry, biological control practitioners and the selected regulatory authority consider them to be realistic and manageable, it is recommended that they be adopted as the official European standard for information requirements for IBCA risk assessment.

Significant progress has also been made towards formulating a workable framework under which future IBCA risk assessments could be conducted (see van Lenteren et al. 2006). This framework attempts to simplify the process of conducting such assessments for IBCAs intended for inundative release, but it is possible that IBCAs for classical biological control could be included in such a scheme. Such a framework would not only aid biological practitioners in their pursuit of conducting a thorough risk assessment, but by having a European framework, release applications would become more uniform in structure and content, thus lending themselves for a faster review process.

Fees

It is clear from the analysis of the regulatory systems in Australia, Canada and the USA that having legislation and administrative bodies to oversee the introduction and release of IBCAs does not necessarily mean that the application process is expensive for the biological control practitioner. Administrative costs in Australia, Canada and the USA are covered by public money via the national governmental bodies and the review process in these countries operates on a voluntary basis, so that scientists are not paid for the reviews they conduct. This leaves the applicant with minimal fees to pay upon dossier submission. In order to avoid biological researchers and industries in Europe being faced with additional administrative fees, it is recommended that a similar system be adopted for Europe. By implementing IBCA regulation via an EU-level administrative body, there would be the possibility of using public money to cover extra administrative costs. Furthermore, evaluation of biological control agents is in the public interest, thus there is justification for support by public funds.

Time frame

For obvious reasons, Europe should endeavour to minimize the time taken for dossier turnaround to avoid delaying the progress of biological control projects. Establishing a legislative and administration system for Europe does not automatically imply that the IBCA release application review process would require protracted periods of time. In New Zealand, there is a legal requirement for ERMA New Zealand to provide a decision within 100 working days of receiving a dossier and in Canada, an applicant may expect to receive a response within 6 months of submitting a dossier. With a simplified and efficient administrative process, Europe could certainly aim to attain equally reasonable and workable time scales.

Availability of information about regulation process to aid applicants

It would be highly beneficial for several reasons to ensure that applicants, as well as the general public, have easy access to information about the regulatory process for IBCA introduction and release into a new area. For example, information should certainly be readily available on the Internet. Information regarding the regulatory processes in Australia, New Zealand, Canada and the USA can be found by performing a quick search on their government websites. New Zealand has an extensive website containing comprehensive information about the roles of ERMA New Zealand and the process of applying for IBCA release approval. In addition, there are numerous guidance documents available for dossier preparation and all previous applications, reviews and decisions are accessible. Europe would certainly benefit from following the lead of AAFC in Canada who recently published a 'Guide for the importation and release of arthropod biological control agents in Canada' (De Clerck-Floate et al. 2006). Not only does this document explain in detail the application and decision-making process for IBCA introduction and release in Canada, but it also provides examples of completed application forms so that applicants are able to clearly see the information requirements together with the methodologies and systems that can be used to gather such data.

Public participation

A troubling issue for the practice of biological control is that in recent years there has been an abundance of criticism pertaining to its potential negative effects on biodiversity whereas, in comparison with some chemical and some mechanical methods of control, biological control is normally regarded as an environmentally benign method of pest control. The public are also aware of the lengthy and costly procedures involved with investigating a potential biological control agent, which only decreases their confidence and support for such a pest control strategy. In order to restore public support, a European regulatory scheme is needed to ensure that biological control practice is safe and that necessary precautions are being taken to prevent any detrimental environmental effects occurring as a consequence of IBCA introductions. This regulatory process needs to be made transparent to the public, allowing for easy access to information so that people can formulate their own informed opinions. Confidence and support would also be enhanced if members of the public were provided with the opportunity to participate in the decision-making process for release applications. Their involvement in the process would help increase general awareness and knowledge of biological control practice, thus helping to raise its profile in society. Achieving the task of incorporating public opinion into the regulatory procedure would be no easy feat. In New Zealand, public hearings are a common occurrence; however, with Europe being composed of 46 countries, arranging public hearings would be a costly, time consuming and near impossible task in terms of the required administration. In Australia and the USA, release applications are placed on the government websites and members of the public are invited to submit their comments via the Internet. This web-based method would seem to be the most appropriate method for Europe to include public participation in their regulatory system. The expert panel could then take comments or concerns from interested members of the public into consideration when reviewing dossiers.

Length of validity of permit

Whereas Canada and the USA assign a validity period to full-release approvals, New Zealand and Australia's release approvals are indefinite, unless, for example, the status of the agent changes. It would be advantageous to implement a system in Europe that allows IBCAs, which have been released safely for several years with no record of non-target impact, to be given an indefinite release approval.

Is there a 'safe list' of IBCAs that are exempt from regulation?

None of the four countries analyzed in this review have a 'safe list' as such, although there are lists available documenting IBCAs that have previously been approved for release. Europe, in fact, already possesses a 'safe' list. In 2002, EPPO published a list of biological control agents widely used in the EPPO region (EPPO 2002) to facilitate decisions on the import and release of biological control agents within EPPO countries. The list specifies indigenous, introduced and established biological control agents and divides them into two parts: (1) commercially used biological control agents and (2) successfully introduced classical biological control agents. It is highly recommended that this list be revived and actively maintained and that specific criteria and data requirements be established for inclusion of a particular IBCA on the list. This list would then potentially serve as a valuable database of information for IBCA releases across Europe as well as an important tool for reviewers of applications and regulators, providing them with access to existing regulatory decisions, both positive and negative, together with their justifications.

Summary of recommendations for a European IBCA regulatory system based on positive features of the Australian, New Zealand, Canadian and USA systems

- A regulatory system should only apply to the import and release of exotic IBCAs into Europe. Native IBCAs should not be subject to restrictions.
- To guarantee harmonized implementation of regulation across Europe, administration should fall under an EU-level governmental body.
- Approval by this EU administrative body for all IBCA introductions should also be a requirement.
- The European regulatory system should be implemented through legislation to ensure harmonization across all member countries.
- Europe should aim to establish an expert panel to conduct science-based reviews of IBCA release applications, as well as to offer a pre-submission advisory service to applicants.

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- The expert panel would provide a recommendation to the EU administrative body regarding release applications. It would then lie in the hands of the European representatives on the EU administrative body to make the official ruling.
- The guidelines compiled as part of the IOBC/WPRS Commission for the Harmonisation of Regulation of Invertebrate Biological Control Agents (Bigler et al. 2005b) should be adopted as the official European standard for information requirements for IBCA risk assessment (provided that industry, biological control practitioners and the selected regulatory authority consider them to be realistic and manageable).
- A European framework under which future IBCA risk assessments would be conducted should also be established. It is recommended that van Lenteren et al. (2006) be employed for this purpose.
- Administrative costs should be covered by public money through the responsible EU administrative body and the review process by the expert panel should be operated on a voluntary basis, thus leaving applicants minimal fees to pay upon dossier submission.
- Europe should endeavour to establish a simplified and efficient administrative process in order to attain reasonable and workable time scales for dossier review.
- The list of biological control agents widely used in the EPPO region (EPPO 2002) should be revived and maintained to serve as a useful regulatory tool as well as an information database for IBCA releases across Europe.

Europe's goal is to develop and implement a harmonized regulatory system for the import and release of IBCAs across all its member countries. Australia, New Zealand, Canada and the USA have all had several years of experience in implementing IBCA regulatory procedures and therefore there is great potential for Europe to benefit from their knowledge. We have proposed the above recommendations for a European system based on our research into the regulatory systems in these four countries and on the features of each system that work well and could potentially be adopted by Europe. Clearly, there will be challenges in introducing a unified scheme into so many different countries. However, if Europe can develop an efficient regulatory process that is scientifically sound and affordable for the biological control practitioner, then it should be possible to overcome such obstacles and gain full support for the implementation of a Europe-wide system.

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